UNITED STATES GOVERNMENT

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

***MEMORANDUM***

TO: The Secretary DATE: February 7, 1969
FROM: Philip R. Lee, M.D. Assistant Secretary for Health and Scientific Affairs
SUBJECT: Task Force on Prescription Drugs–Final Report

In May of 1967, upon a directive from the President, the Task Force on Prescription Drugs was established to undertake a comprehensive study of the problems of including the costs of prescription drugs under Medicare.

During the ensuing 20 months, the Task Force carried out a number of studies involved in this complex assignment. Based on this work, we have already completed and submitted five interim reports.

I am now pleased to transmit for your consideration the final report, which summarizes the major findings and recommendations previously included in the interim reports. Perhaps the most significant are these:

- The finding that a drug insurance program under Medicare is needed by the elderly and would be both economically and medically feasible, and the recommendation that such a program be instituted.
- The finding that the once-confusing matter of clinical equivalency is far less complex than had been anticipated, and that as a result of current laboratory and clinical studies–initiated in large part in response to requests by the Task Force–the problem is well on its way to a solution.

A number of the recommendations submitted by the Task Force have been acted upon by Secretary Gardner and Secretary Cohen. Some of these have involved actions

within the Department of Health, Education, and Welfare. Others have involved close and effective cooperation with private organizations and institutions.

Some of the important recommendations have been communicated to all the physicians of the country, as well as to the deans of relevant professional schools and leaders of professional health organizations. Many constructive suggestions have been received as a result of these efforts.

Several recommendations will require legislative action and therefore have not yet been implemented. Still others will require formal agreements among various Federal Departments and agencies; action on these was deferred by Secretary Cohen because of the long-term commitments which would be involved.

In addition to these reports, the Task Force and its staff have prepared a series of background papers on various aspects of the use, production, distribution, and prescription of drugs, and the nature of current drug insurance programs. Four of these volumes–*The Drug Users*, *The Drug Makers and the Drug Distributors*, *The Drug Prescribers*, and *Current American and Foreign Programs*–have already been published. A fifth–on approaches to drug insurance design–is now being completed.*

It is our hope that these reports and background publications will be useful as the basis for careful analysis and discussion, and that they will serve as a contribution to the improvement of the quality of health care throughout the Nation.

## *TERMINOLOGY*

The term *generic equivalents* is not used in the body of this report. Although it has been widely utilized, it has been given so many

*Editor's note: Each of these is now available.

different interpretations that it has become confusing. Instead, the following terms are used:

*Chemical equivalents*–Those multiple-source drug products which contain essentially identical amounts of the identical active, ingredients, in identical dosage forms, and which meet existing physicochemical standards in the official compendia.

*Biological equivalents*–Those chemical equivalents which, when administered in the same amounts, will provide essentially the same biological or physiological availability, as measured by blood levels, etc.

*Clinical equivalents*–Those chemical equivalents which, when administered in the same amounts, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease.

The following are terms also used:

*Generic name*–The *established* or *official* name given to a drug or drug product.

*Brand name*–The registered trademark name given to a specific drug product by its manufacturer.

*Molecular manipulation*–A minor modification in the molecular structure of a chemical, yielding a new and patentable product which may or may not offer a significant therapeutic advantage over a related drug already on the market.

*"Me-too" or "duplicative" drug*–A new drug, often made by means of molecular manipulation, which offers no significant therapeutic advantage over a related drug already on the market. (Chemical equivalents, since they are chemically identical, are not considered to be ''me-too'' products.)

*Rational prescribing*–Prescribing the right drug for the right patient, at the right time, in the right amounts, and with due consideration of relative costs.

## *SUMMARY OF MAJOR FINDINGS*

### *The Drug Users*

1. The requirements for appropriate prescription drug therapy by the elderly are very great–far greater, in fact, then those of any other group–and many elderly men and women are now unable

to meet those needs with their limited incomes, savings, or present insurance coverage. Their inability to afford the drugs they require may well be reflected in needless sickness and disability, unemployability, and costly hospitalization which could have been prevented by adequate out-of-hospital treatment.*

2. In order to improve the access of the elderly to high quality health care, and to protect them where possible against high drug expenses which they may be unable to meet, there is need for an out-of-hospital drug insurance program under Medicare.

***The Drug Makers***

3. Since important new chemical entities represent only a fraction–perhaps 10 to 25 percent–of all new products introduced each year, and the remainder consists merely of minor modifications or combination products, then much of the drug industry's research and development activities would appear to provide only minor contributions to medical progress.
4. To the extent the industry directs a share of its research program to duplicative, noncontributory products, there is a waste of skilled research manpower and research facilities, a waste of clinical facilities needed to test the products, a further confusing proliferation of drug products which are promoted to physicians, and a further burden on the patient or taxpayer who, in the long run, must pay the costs.
5. The exceptionally high rate of profit which generally marks the drug industry is not accompanied by any peculiar degree of risk, or by any unique difficulties in obtaining growth capital. Industry profits have not been significantly reduced by new governmental regulations concerning drug safety, drug efficacy, or drug advertising.

***The Drug Distributors***

6. Products marketed by physician-owned repackaging companies should be considered unacceptable for reimbursement in any Medicare program except in those instances in which the

*In the original report this summary provided a page reference. That was not possible in this format.

Secretary of Health, Education, and Welfare determines that the availability of products marketed by such companies is in the public interest.

7. There is a need for medical associations, pharmacy associations, and consumer groups, working together at the local level, to develop mechanisms whereby patients may obtain information on local prescription prices, especially for long-term maintenance drugs.

***The Drug Prescribers***

8. Few practicing physicians seem inclined to voice any question of their competency in the field of therapeutic judgments. The ability of an individual physician to make sound judgments under quite confusing conditions, however, is now a matter of serious concern to leading clinicians, scientists, and medical educators.

***Current American and Foreign Programs***

9. In Medicaid and other State public assistance programs, no single method will by itself guarantee program efficiency, but without at least two features–reasonable formulary restrictions and effective data processing procedures–program controls will be ineffective. Although a co-payment requirement may not be widely acceptable in public assistance drug programs, its value in controlling costs in other programs seems evident.
10. Establishment of an out-of-hospital prescription drug program for the elderly or for other population groups has been shown to be economically feasible in many countries.
11. Rational prescribing, with due regard to quality of health care as well as to program costs, can be improved through the cooperation of physicians, pharmacists, drug manufacturers, and a governmental agency.
12. Reasonable program costs appear to be associated with (a) the use of a formulary developed by or in cooperation with the medical community, (b) the use of co-payment or co-insurance, (c) the use of utilization review procedures to prevent or minimize irrational prescribing, (d) the use of appropriate electronic or other data processing methods, with appropriate drug coding techniques, (e) simplified determination of beneficiary

eligibility, (f) population coverage which obviates the adverse selection of high-risk beneficiaries, (g) the use of a vendor payment formula based on actual acquisition cost verified by field audits rather than any catalog or wholesale list price, and (h) operation with the program serving as the legal purchasing agency, with utilization of competitive and negotiated bids, rather than merely as the reimbursing agency.

13. A permanent mechanism is needed at the Federal level to collect, analyze and exchange information, and to provide effective coordination of drug-related activities among the agencies involved.

***Drug Quality***

14. On the basis of available evidence, lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health.
15. The drug quality studies undertaken by the Food and Drug Administration are expected to be adequately if not completely up-to-date by 1971, and thus will provide reasonable assurance of uniform drug quality by that time.
16. There should be uniform standards of quality and efficacy for each drug in any federally-supported drug program. It would be inappropriate to provide for differential cost ranges for the products sold under brand or generic names.

***Generic Prescribing and Drug Costs***

17. The use of low-cost chemical equivalents can yield important savings, especially in the case of patients with cardiovascular disease, kidney disease, arthritis, and mental and nervous conditions. The use of such products should be encouraged wherever this is consistent with high-quality health care.

***Formularies***

18. In general, American physicians have found a formulary acceptable and practical, especially when it is designed by their clinical and scientific colleagues serving on expert committees, when quality is considered at least as important as price, when the formulary can be revised at appropriate intervals, and when there are provisions for prescribing unlisted drug products where special clinical conditions so demand.

19. The use of a formulary is not a mark of second-class medicine, but is, in fact, associated with the provision of the highest quality of medicine in the outstanding hospitals in the Nation.
20. Although use of a formulary is not a guarantee of high quality medical care, rational prescribing, effective utilization review, and control of costs, the achievement of these objectives in a drug program is difficult if not impossible without it.

***Quality and Cost Standards***

21. The exclusion of certain combination products, duplicative drugs, and noncritical products from Federal reimbursement would contribute significantly to rational prescribing, and moreover, it seems reasonable to assume this could yield overall savings of at least 10 percent.
22. Establishing product cost ranges reflecting the cost of drugs generally available by their generic names would save approximately 5 percent at the retail level.
23. Although significant program savings could be achieved through the application of techniques designed to improve the efficiency of vendor operations, it is impossible at this time to estimate the extent of these savings.
24. Considerable time would be required to develop all the necessary administrative mechanisms. Therefore full implementation of such provisions as applied to Federal reimbursement for prescribed drugs cannot be assured in less than two years after enactment of appropriate legislation.
25. Any necessary increases in Federal expenditures for the improvement of drug standards and quality control will have benefits which apply to all users of prescription drugs and should not be attached to the implementation of cost standards for drugs supplied in Federally-assisted programs.
26. Establishment of reasonable cost and charge ranges for drugs provided under the Medicare, Medicaid, and Maternal and Child Health programs is feasible, and would reduce the cost of drugs to the Federal and State governments without sacrifice of quality.

***Drug Classification and Coding***

27. Within a few years, it may be expected that prescription drug benefits under existing public and private programs will involve several hundred million prescriptions annually. Without a universal coding, classification and identification system–a common language for communicating essential information–the administrative and accounting costs for processing such a volume will inflate program costs beyond acceptable limits.

***Utilization Review***

28. There is an urgent need for further research to develop and test various approaches to effective utilization review–approaches which would be most acceptable to physicians, pharmacists, consumers and others, and which would obtain their effective support.

***Drugs Under Medicare: The Issue of Comprehensive Coverage***

29. Because of the numerous and complex administrative problems and the high program costs involved in providing drug coverage under Medicare, it would be desirable–at least at the outset–to provide the benefit on a less-than-comprehensive basis.

***Drugs Under Medicare: Coverage Under Part A or Part B***

30. While it would be feasible to provide coverage of out-of-hospital prescription drugs under either the hospital insurance (Part A) or medical insurance (Part B) programs of Medicare, there would be significant advantage, in terms of beneficiary eligibility and financing, in providing such coverage under the hospital insurance program.

***Drugs Under Medicare: Alternative Proposals for Coverage***

31. In order to achieve maximum benefits with whatever funds may be available, and to give maximum help to those of the elderly whose drug needs are the most burdensome, particular consideration should be given to providing coverage at the

outset mainly for those prescription drugs which are most likely to be essential in the treatment of serious long-term illness.

32. The use of an annual deductible to control costs presents opportunities that warrant further consideration.
33. Restricting benefits to those aged 70, 72, or more would reduce the size and cost of the program, but this is not a preferred approach at this time.

***Drugs Under Medicare: Program Administration***

34. It would be preferable for the vendor rather than the beneficiary to have major responsibility for keeping needed records and initiating claims, and to be reimbursed by the program.
35. Because of the large number of claims which would be involved, a suitable automated data processing system could play a vital role in claims processing and other administrative activities, and should be developed and adequately tested.
36. To the extent that appropriate utilization review methods are developed, these should be applied in a Medicare drug program.

***Drugs Under Medicare: Program Reimbursement***

37. Reimbursement for product cost, as one element in the total cost of a prescription, may be considered on the basis of (a) ''usual and customary'' charges, (b) listed wholesale price, (c) actual acquisition cost as verified by audit, or (d) a fixed program payment. Preference would be determined by the nature of the program.
38. Reimbursement for product cost should be based on the cost of the least expensive chemical equivalent of acceptable quality generally available on the market.
39. Since the expressed purpose of the social security program is to provide assistance to beneficiaries, wherever possible, within the framework of the existing health care system, the direct purchase of drugs by the Federal Government for Medicare beneficiaries is not recommended at this time, but this approach deserves further study.
40. The preferred method of reimbursing dispensing costs would depend on the nature of the program. If the program provides for a specific dispensing allowance to be paid to the drug vendor, rather than payment to the beneficiary, either a

percentage markup, or a fixed dispensing fee would be feasible, with a fixed fee approach being preferable.

41. Any drug insurance program instituted under Medicare should include cost-sharing provisions, such as co-payment or co-insurance.
42. Consideration should be given to the use of restrictions on maximum prescription quantities or on maximum prescription prices as additional cost-sharing approaches.

***Organization of HEW Pharmaceutical Activities***

43. No gain–and a substantial loss–in operating effectiveness would result from the organizational association of all pharmaceutical and related activities.
44. The drug development and screening programs of the National Institutes are integral parts of the biomedical research effort of the NIH and should remain the responsibility of these respective units.
45. The manpower development activities of the NIGMS (support of the pharmacology-toxicology centers) and of the Bureau of Health Manpower of the NIH are logical parts of the total responsibilities of these two units. Transfer of these activities to related activities of the FDA would not yield adequate benefits to warrant such an organizational change. The pharmaceutical-related activities of the Bureau of Manpower should be administered as part of the total effort to expand needed health manpower by that bureau.
46. The gathering, processing and dissemination of scientific information by the Consumer Protection and Environmental Health Service and its constituent, the Food and Drug Administration; by the National Library of Medicine; and by the National Institute of Mental Health are in each instance activities that flow logically out of other responsibilities of these units. These informational activities should be retained in their present organization.
47. The regulatory activities of the DBS are *not* logically a part of the biomedical research activities of the NIH. The DBS, however, does carry on research and drug development activities related to the central functions of the NIH, and it benefits materially from association with the research staffs of several Institutes of the NIH. Some advantages would be gained

by associating the regulatory activities of DBS with those of FDA. The DBS needs at times the regulatory skills of the FDA. But such transfer of the regulatory activities of DBS from NIH would result in the undesirable disassociation of these regulatory activities from the supporting research activities of NIH, and would cause a substantial loss in morale and probably a loss in key professional personnel. For these reasons, this action is not recommended.

48. No clearly apparent benefits could be derived from the separation of drug regulatory activities from food regulatory activities that would offset the economy and efficiency now achieved through the maintenance of closely related investigatory, research, and regulatory staffs.

## *SUMMARY OF RECOMMENDATIONS*

### *The Drug Makers*

1. The Department of Health, Education, and Welfare should conduct a continuing survey of drug costs, average prescription prices, and drug use.
2. The Secretary of Health, Education, and Welfare should call one or more conferences with representatives of the drug industry, pharmacy, clinical medicine, and consumer groups to consider–
   a. Provision of incentives to the drug industry to invest more research effort in products representing significant improvements to therapy and less in duplicative, noncontributory drug products and combinations.
   b. Development of a registration and licensing system under which no drug product would be permitted in interstate commerce unless produced under quality control standards set by the Secretary of Health, Education, and Welfare.
   c. Limitation of free drug samples, by industry agreement or legislation, to those specifically requested by prescribers.
   d. Development of more effective methods for ascertaining actual acquisition costs of prescription drugs.
3. The Secretary of Health, Education, and Welfare should call for a joint study by the Department of Health, Education, and

Welfare, the Department of Commerce, the Department of Justice, the Federal Trade Commission, and other Federal agencies to consider–

a. The substantial differences in the prices at which drug products are offered to community pharmacies and to hospitals and government agencies.
b. The substantial differences in the prices at which drug products are offered to American and foreign purchasers.
c. Revision of current patent and trademark laws on prescription drugs.

***The Drug Distributors***

4. The Congress should enact legislation requiring that the containers of all dispensed prescription drugs be labeled with the identity, strength and quantity of the product, except where this is waived upon specific orders of the prescriber.
5. Encouragement should be given to the wider use of prepackage dispensing, in which manufacturers prepare and pharmacists dispense tablets and capsules in precounted form, in sealed, prelabeled containers, and in such numbers as conform to those most frequently prescribed by physicians.
6. The National Center for Health Services Research and Development should develop and support research to improve the efficiency and effectiveness of community and hospital pharmacy operations.
7. The Bureau of Health Manpower should support–

   a. The development of a pharmacist aide curriculum in junior colleges and other educational institutions.
   b. The development of appropriate curricula in medical and pharmacy schools for training pharmacists to serve as drug information specialists on the health team.
   c. A broad study of present and future requirements in pharmacy, adequacy of current pharmacy education, and the educational changes which must be made.

8. The Health Services and Mental Health Administration should support studies of state laws, regulations, and codes, with priority given to the establishment of model State licensing laws, uniform reciprocity standards, and provisions for the utilization of pharmacy aides.

***The Drug Prescribers***

9. The Department of Health, Education, and Welfare should provide expanded support to medical schools, enabling them to include a course in clinical pharmacology as an integral part of the medical curriculum.
10. The Department of Health, Education, and Welfare should establish or support a publication providing objective, up-to-date information and guidelines on drug therapy, based on the expert advice of the medical community.
11. The Department of Health, Education, and Welfare should support the efforts of county medical societies, pharmacy and therapeutics committees, medical foundations, and medical schools in taking the responsibility for providing continuing education to physicians on rational prescribing.
12. The Secretary of Health, Education, and Welfare should be authorized to publish and distribute a drug compendium listing all lawfully available prescription drugs, including such information as available dosage forms, clinical effects, indications and contraindications for use, and methods of administration, together with price information on each listed product, in readily accessible and comprehensive form.

***Current American and Foreign Programs***

13. The Federal Interdepartmental Health Policy Council should concern itself with the coordination of all ongoing Federal prescription drug purchase and reimbursement programs. A special subcommittee of the Council should be appointed for this purpose.

***Drug Quality***

14. The present clinical trials to determine the biological equivalency of important chemical equivalents should be continued by the Department of Health, Education, and Welfare on a high priority basis.
15. Adequate financial support should be provided to the Food and Drug Administration for necessary educational and inspection operations so that acceptable quality control methods can be instituted and properly maintained in all drug manufacturing and packaging establishments.

16. The Food and Drug Administration should be authorized to provide additional support, including grants-in-aid, to State and local agencies in order to improve quality control of prescription drugs in intrastate commerce.

***Classification and Coding***

17. The Department of Health, Education, and Welfare, the Department of Defense, and the Veterans Administration should test the proposed drug classification system to determine the feasibility of its eventual use in all public and private drug programs.
18. a. An appropriate identifying code number should be made part of all drug labels, package inserts, catalogs and advertising.
    b. An appropriate coding system should be developed and tested by government and industry for this purpose.
    c. After consideration of the results of this test, appropriate legislation should be introduced to require coding of all drug products in interstate commerce.
19. The drug code adopted by government and industry should be utilized in the National Drug Code Directory.

***Utilization Review***

20. The National Center for Health Services Research and Development, in cooperation with State and local medical groups, community pharmacies, hospitals, and consumer groups, should support pilot research projects on prescription drug utilization review methods.

***Organization of HEW Pharmaceutical Activities***

21. The present complex of activities now assigned to the Food and Drug Administration should continue to be administered by that agency.
22. The Social Security Administration should undertake continuing responsibility for the surveillance of drug costs, average prescription prices, and drug use.
23. Efforts should be strengthened to assure that the skills of experts both within and outside of the Department of Health,

Education, and Welfare are used to augment the scientific capabilities of the Food and Drug Administration.

24. Legislation should be enacted to authorize establishment within the Food and Drug Administration of a clinical and laboratory facility to provide the necessary opportunities for research by highly qualified basic scientists and clinicians.
25. The Secretary of Health, Education, and Welfare should, after consultation with representatives of the drug industry, pharmacy, clinical medicine, and consumer groups, appoint a study group to reappraise the efficiency of methods now used by the Division of Biologics Standards and the Food and Drug Administration to evaluate the safety and effectiveness of pharmaceuticals. The participants should direct attention to the appropriateness of the three existing classifications of pharmaceuticals–new drugs and ''not new'' drugs, certifiable products, and biologics. The study group should also consider the feasibility of developing a registration and licensing system which would assure that all drugs marketed in interstate commerce are produced under adequate quality control standards.

## *INTRODUCTION*

On January 23, 1967, in his Older Americans Message to the Congress, President Lyndon B. Johnson focused national attention on the heavy burdens borne by many elderly men and women in attempting to pay the costs of prescription drugs. At the same time, he directed the Secretary of Health, Education, and Welfare to ''undertake immediately a comprehensive study of the problems of including the cost of prescription drugs under Medicare.''

Within this Department, informal studies in this complex and important area had already been underway for many months. These were quickly intensified by the President's directive.

On May 31, 1967, John W. Gardner–then Secretary of Health, Education, and Welfare–established the Task Force on Prescription Drugs. It consisted originally of four Assistant Secretaries, the Commissioner of Social Security, the Commissioner of Food and Drugs, the Acting Commissioner of Welfare, and the Surgeon General of the Public Health Service, with a specially-selected technical staff.

> ''The Task Force,'' he emphasized, ''has no prior commitment to recommend for or against the inclusion of prescription drugs in the Medicare program. Its directive is first to investigate and then to make whatever recommendations it considers appropriate.
>
> ''The Task Force will examine a wide range of factors which are involved in the use of prescription drugs and will offer its recommendations within six months. The problems are numerous and complex. Some answers may be found speedily; others may take many months, possibly even years, of work, including laboratory research and clinical trials.
>
> ''In all of its work, I have asked the Task Force to measure the value of possible solutions not only in terms of dollars to be saved, but in the quality of health care to be delivered.''

The scope and complexity of the assignment was by no means exaggerated by the Secretary. Inevitably, as formal operations were begun by the Task Force, and as additional information was requested by the Congress, it became essential to broaden the study to cover a large number of closely interrelated factors–the use of prescription drugs by the elderly, and their ability to meet drug expenses; the health needs of the elderly; the prescribing patterns of physicians, and the sources of drug information available to them; the nature of drug manufacture, and of drug promotion, drug advertising, drug pricing, and drug profits; the nature of drug distribution; the pharmacological aspects (including the hotly controversial matter of clinical equivalency); the role of formularies; the nature of current drug insurance programs, private and governmental, in this country and abroad; and the various alternatives involved in program financing, administration, reimbursement, classification, coding, and other aspects of drug insurance.

To undertake its studies in these and other fields, the Task Force enlisted the advice and guidance of many highly qualified experts, both governmental and nongovernmental. (A list of the non-governmental experts is presented at the end of this report.) We are most grateful to all of them for their invaluable assistance. None of them, of course, may be held responsible for any conclusions reached by the Task Force.

Because of the scope of these operations, no attempt was made to present final recommendations at the end of six months, as was

originally contemplated. Instead, a series of five interim reports were published, beginning in March of 1968.

This Final Report contains most of the material published in interim form–much of it updated and expanded–together with some additional material.

It includes those findings which the Task Force believes to be particularly significant.

It includes recommendations for action–recommendations which, in some instances, are already being implemented by the various agencies of the Department.

Perhaps most significant are these:

- The finding that a drug insurance program under Medicare is needed by the elderly, and would be economically and medically feasible.
- The finding that the once-confusing matter of clinical equivalency is far less complex than had been anticipated, and that as a result of current laboratory and clinical studies–initiated in large part in response to requests by the Task Force–the problem is well on its way to solution.

In addition, much basic material–a substantial portion of it hitherto unavailable–has been obtained on various aspects of drug production, drug distribution, drug prescription, drug use, and drug insurance. This information appears to have great value for the Congress, many State and Federal governmental agencies, the medical and pharmacy communities, the drug industry, health insurance organizations, health educators, and consumer groups. It is being presented in a series of Task Force background papers, four of which have already been published and a fifth which is now in press.

It is our hope that all these publications–this Final Report and the background papers–will serve as the basis for careful analysis and discussion in the months and years to come.

More important, it is our hope that these publications, and the dedicated efforts of the many individuals who made them possible, will help to improve the health care not only for the elderly but for all Americans.

(Signed) Philip R. Lee, M.D.

## *CHAPTER 1*
## *THE DRUG USERS*

The elderly in the United States–those aged 65 or more–represent only a relatively small proportion–about 10 percent–of the total population of this country.

But their inordinate health needs, their high health care costs in general and high drug costs in particular, and their limited financial resources combine to create a serious and sometimes a devastating medical and economic problem far out of proportion to their numbers.

For many elderly people, illness serves as a major cause of their poverty by reducing their incomes, while poverty serves as a major contributory cause of illness by making it difficult for them to obtain adequate health care.

Yet it is not only the totally impoverished or the totally incapacitated who are in a precarious position. There are many elderly men and women who have some income and some savings–who may even have sufficient Medicare or other insurance to protect them against the bulk of hospital and medical costs of a brief illness–but who cannot pay for the out-of-hospital drugs and other costs of a long-continuing chronic illness without seeing their financial assets eroded or totally dissipated.

### *Numbers and Health Needs of the Elderly*

There are now more than 19 million Americans over the age of 65. Among them, about 57 percent are women and 43 percent are men. This disproportion in sex distribution has been increasing steadily since about 1930–a trend of importance for any prescription drug study, since the use of these drugs by women is significantly higher than that by men.

In connection with the elderly, the term *aging* has often been considered synonymous with *illness*. There is, in fact, no necessary relationship between the two, but it is undeniably a fact that illness strikes the elderly far more frequently than it does younger age groups.

Approximately 80 percent of the elderly–in comparison with 40 percent of those under 65–suffer from one or more chronic diseases and conditions. Arthritis and rheumatism afflict 33 percent; heart disease, 17 percent; high blood pressure, 16 percent; other cardiovascular ailments, 7.5 percent; mental and nervous conditions,

10.5 percent; hearing impairments, 22 percent; and visual problems, 15 percent.

Many of these conditions can be controlled or alleviated by modern medical care, especially by the proper use of drugs. This is reflected in the heavy expenses of the elderly for health care, and particularly in their heavy expenses for drugs.

### *Health Expenditures*

Between 1950 and 1966, total national expenditures for health services and supplies–including hospital costs, physicians' fees, and drug costs–rose from $11.9 billion to $41.8 billion. (Per capita expenditures increased from $78.20 to $212.47.) In that same period, expenditures for out-of-hospital prescription drugs rose from $1.0 billion to $3.2 billion. (Per capita expenditures increased from $6.85 to $16.05.)

The increase in drug expenditures has resulted in part from a greater number of prescriptions per individual–an average of about 2.4 acquisitions per capita in 1950 and 4.6 in 1966–as well as from a significant rise in the average cost of prescriptions.

In 1950, a number of independent surveys reported the average cost of all prescriptions at the retail level was between $1.66 and $2.03. In 1966, independent surveys estimated the average was between $3.26 and $3.59. A special study conducted for the Task Force showed that the average prescription cost for the elderly in 1966 was even higher–$3.91.

### *Distribution of Drug Expenditures*

If drug use were equally distributed among all groups–that is, 4 to 5 prescriptions per year at a cost of $3 to $4–there would be no major problem for the elderly. But this is far from the actual situation.

Although the elderly represent slightly less than 10 percent of the total population, they account for about 22 percent of all out-of-hospital prescriptions and about 25 percent of all out-of-hospital prescription drug expenditures.

A nationwide study by the National Center for Health Statistics in fiscal year 1965 showed the following (see Table 1):

- The average number of acquisitions–i.e., the number of prescriptions or refills–for the elderly was more than twice that for the total population, and nearly three times that for those under 65.

- The average number of acquisitions for elderly women was nearly 50 percent more than the number for men.
- The per capita expenditure for prescription drugs for the elderly was almost three times greater than that for the total population, and more than three times greater than that for those under 65.
- The per capita expenditure for elderly women was more than one-third higher than that for elderly men.
- The per capita expenditure for the elderly with severe disabilities was nearly three times greater than that for those with no disabilities.

These 1964-65 data indicate that for the relatively few elderly with no chronic conditions, the annual cost for prescribed medicines was $3.60 per capita. For those with one or more chronic conditions, the number of acquisitions rose to 13.5 and the annual cost to $48.80.

TABLE 1. Average Number of Acquisitions and Annual Cost of Prescribed Drugs, Per Person by Selected Characteristics, Fiscal Year 1965.

| Characteristics | No. of Acquisitions[a] | | | Annual Cost | | |
|---|---|---|---|---|---|---|
| | All Ages | Under 65 | 65 and Over | All Ages | Under 65 | 65 and Over |
| All Persons | 4.7 | 4.0 | 11.4 | $15.40 | $12.77 | $41.40 |
| Sex | | | | | | |
| Male | 3.7 | 3.1 | 9.3 | 12.00 | 9.88 | 34.70 |
| Female | 5.6 | 4.8 | 13.1 | 18.60 | 15.49 | 46.70 |
| Color | | | | | | |
| White | 4.9 | 4.2 | 11.5 | 16.40 | 13.62 | 42.60 |
| Nonwhite | 3.1 | 2.7 | 10.2 | 7.80 | 6.57 | 26.90 |
| Geographic Region | | | | | | |
| Northeast | 4.4 | 3.8 | 10.6 | 13.30 | 10.80 | 37.00 |
| North Central | 4.4 | 3.8 | 10.9 | 15.00 | 12.37 | 39.90 |
| South | 5.3 | 4.5 | 13.6 | 17.50 | 14.64 | 47.40 |
| West | 4.3 | 3.7 | 9.7 | 15.30 | 12.93 | 40.00 |
| Disability–Men | | | | | | |
| None | | | | 14.80 | | 19.40 |
| Mild | | | | 33.50 | | 40.90 |
| Moderate | | | | 33.60 | | 40.80 |
| Severe | | | | 71.70 | | 71.00 |
| Disability–Women | | | | | | |
| None | | | | 23.20 | | 34.00 |
| Mild | | | | 50.00 | | 64.40 |
| Moderate | | | | 63.40 | | 67.60 |
| Severe | | | | 101.40 | | 94.70 |

[a] New prescriptions or refills.

When the condition was sufficiently severe to limit major activity completely, acquisitions averaged 21.7 prescriptions, and costs averaged $78.80. Similarly, the average cost of a prescription was higher for persons with chronic conditions–$3.60 for persons with no such conditions, $4 for those with one or more conditions, and $4.10 for those with complete limitation in their major activity. The data also indicated that prescription expenses of those of the elderly with severe chronic conditions–about 15 percent of all elderly persons–were over 6 times as great as the expenses of younger people.

In general, the survey showed, total prescription drug expenditures in all age groups were higher for women than for men, for whites than for nonwhites, and for those in the South and West. The higher expenditures for whites appear to be a reflection of their greater affluence–their greater ability to seek medical care and to afford drugs rather than greater health needs. The high costs in the South appear to be related to exceptionally heavy utilization, while in the West they reflect lower utilization but much higher costs per prescription.

Similarly, although the burden of drug costs falls most heavily upon the elderly, it does not fall evenly upon these individuals.

A 1968 estimate, for example, indicates that 20 percent of the elderly will have no drug expenses, while the costs will be less than $50 for 41.5 percent, between $50 and $99 for 19 percent, between $100 and $249 for 15.5 percent, and $250 or more for 4 percent.

A recent investigation, carried out on a limited group in Pennsylvania, indicated that, among the elderly who actually obtained prescription drugs, about 2 percent accounted for about 21 percent of the total cost, and about 10 percent of the individuals accounted for about 47 percent of the cost.

An earlier study by the National Health Survey in 1962 of the expenses for prescription and nonprescription drugs found that 24 percent of the elderly had no drug expenses, 40 percent had annual expenses which were less than $50, 17 percent had expenses between $50 and $99, and 18 percent had expenses of $100 or more. Among these 18 percent, the expenses were $100 to $249 for 14.7 percent, $250 to $499 for 2.9 percent, and $500 or more for 0.5 percent.

### *Financial Resources of the Elderly*

The size of drug bills for the elderly represents only one phase of the problem. Intimately related is their ability to pay those bills.

Since July 1, 1966, implementation of the Medicare program has substantially increased the ability of many elderly men and women to meet their doctor and hospital bills, not entirely but in large part. Expenditures for out-of-hospital prescription drugs, however, are not covered by the present Medicare law, and it has been necessary for elderly patients to utilize other sources.

*Income*. In 1966, half of the families headed by an elderly individual had total incomes–including Social Security payments–of less than $3,645, or $70 a week. For elderly men and women living alone, or with someone not a relative, more than half had incomes of less than $1,500, or about $30 a week.

In spite of recent improvements in OASDI benefit levels, the elderly remain among the most impoverished groups in the population. It is estimated that as of January 1, 1969, almost 3 million elderly persons were living in poor households, as measured by the Social Security Administration's poverty index. Counting also elderly persons in institutions and those with incomes below the poverty level who are living in households whose total income is above that level, a little over 7 million elderly persons, or 36 percent of the total elderly population, were poor.

Among social security beneficiaries, although benefit income kept some 6.8 million out of poverty, another 5.8 million or 36 percent remained poor. An additional 3 million were in the near-poor group, only a little better off.

*Assets*. Recent studies have shown that the average per capita amount of savings and other assets held by the elderly is about $15,000.

But 30 percent of the elderly have assets of less than $1,000 apiece. For them, a serious illness could wipe out their meager savings in a few months.

*Health Insurance*. Health insurance through Blue Cross, Blue Shield, commercial insurance companies, group practice plans and other organizations is available to many of those over the age of 65, but provision of prescription drugs–except to hospitalized patients–is limited.

Where out-of-pocket drug expenses are covered, these are generally included in major medical policies involving deductibles of $100, $250, or $500–useful only in so-called ''catastrophic'' illnesses.

Recently, drug insurance programs have been developed to provide adequate coverage of out-of-hospital drug costs, but membership in

the plans is usually limited to members of employed groups, and few of these are in the older-age group.

As of the end of 1966, while about 51 percent of the elderly had some form of hospital insurance complementary to Medicare, only about 9 percent had insurance coverage for their out-of-hospital prescription drugs; drug coverage ranked below private-duty nursing, visiting-nurse services and nursing-home care in extent of coverage.

*Tax Relief*. To the extent that expenses for drugs are included as deductions on income tax returns, reduced income tax payments represent a source of payment for these drugs.

For the elderly, such relief obtained through Federal income tax deductions has been estimated to represent about 8 percent of drug expenditures. But these savings benefit only those elderly individuals who receive enough income to require income tax payments, and would be of little importance to those with low incomes. Data are not available on the extent of such savings achieved through deductions on State income taxes.

*Free Drugs*. From the 1964-65 study of the National Center for Health Statistics, it appears that about 3 percent of the elderly received their drugs at no cost from their physicians.

*Public Assistance*. About 6 percent in 1964-65 obtained prescription drugs from State or local welfare agencies or similar sources. The provision of free drugs through welfare agencies–under Medicaid or other Federal, State or local programs–may solve the problem as it directly affects some of the elderly. The basic economic problem is not solved, however, but merely shifted from the elderly to the taxpayers.

It is estimated that in calendar year 1967, the latest year for which figures are available, expenditures for drugs for elderly persons through State vendor payment drug programs for welfare recipients in the Federally-aided public assistance categories totalled about $105 million. The Federal share of these payments was about 53 percent. About 1.3 million older people received these benefits, which are payable under 41 State or territorial assistance programs. In addition, several of the assistance programs included an allowance for drug costs in their cash payments to older people.

*Out-of-Pocket Costs*. In enabling the elderly to meet their out-of-hospital prescription drug expenses, the combined impact of insurance coverage, tax relief, free drugs, and public assistance does not seem to be substantial, covering only about 20 percent of total costs.

The remainder–about 80 percent–must be met by out-of-pocket expenditures from income and assets. For those over 65, these financial resources are rarely substantial.

Thus, the elderly, with limited income, limited savings, and minimal protection from health insurance and other sources, are obliged to face the burdens of drug costs which are far heavier on a per capita basis than those which weigh on their fellow citizens, who in most cases are not only younger, but also healthier and wealthier.

***Patterns of Drug Use by the Elderly***

Essential for an effective attack against the drug problems of the elderly are detailed, objective data on the drugs they actually use and the costs of these prescriptions.

In 1966, for example, the elderly obtained about 225 million out-of-hospital prescriptions at a total retail cost of almost $900 million, involving many thousands of different drug products. But this knowledge is not enough.

It is necessary to know–

- which drugs, by brand or generic name, were dispensed for the elderly;
- which were utilized most frequently;
- which diseases accounted for the greatest drug utilization;
- which drugs were most frequently involved in long-term maintenance therapy;
- how much each of these drugs cost at the wholesale level, and at the retail level; and
- to what extent drug costs could be reduced if low-cost chemical equivalents were used wherever they were available.

To obtain the needed information, the Task Force requested the Public Health Service to undertake a special study, with major responsibility assigned to the Health Economics Branch of the Division of Medical Care Administration, and assistance provided by other agencies within the Bureau of Health Services, and by the Food and Drug Administration.

The project–probably the first of its kind ever undertaken–was aimed at developing a master list of the drugs which were most frequently prescribed and dispensed for the elderly in 1966, and which would account for about four-fifths of their drug use during that year.

*The Task Force Master Drug List*. As developed for the Task Force, the Master Drug List (MDL) contained the 409 most frequently prescribed drugs dispensed to the elderly in 1966. These accounted for 174.7 million, or 88 percent, of all prescriptions dispensed by community pharmacies for the elderly in that year, and for $682.3 million, or 88 percent, of their prescription drug costs at the retail level.

Included among the 409 products were 379 which were dispensed under their brand names. These accounted for more than 90 percent of the total number of MDL prescriptions, about 90 percent of the total acquisition cost to retailers, and 95 percent of the total retail cost to patients.

Among these were 86 products which were dispensed under their brand names, but for which chemical equivalents were available–often but not always at lower cost–and could have been prescribed under generic names. They accounted for about 29 percent of the total number of prescriptions, 27 percent of the total acquisition cost to retailers, and 27 percent of the retail cost to patients.

Also included were 30 drugs which were dispensed under their generic names. They accounted for about 10 percent of the number of prescriptions, 10 percent of the total acquisition cost, and 5 percent of the total retail cost.

*Average Prescription Cost*. For all 409 MDL drugs, the average cost per prescription was $3.91. For the 379 drugs dispensed under brand name, it was $4.11. For the 30 drugs dispensed under generic name, it was $2.02.

*Most Widely Used Drugs*. The 10 most frequently used products–headed by an oral antidiabetic agent, and including two tranquilizers, two diuretics, an analgesic, an anti-arthritic agent, a cardiac drug, and two sedatives–accounted for 20 percent of the total number of MDL prescriptions, 21.6 percent of the total acquisition cost to retailers, and 20.7 percent of the total retail price to consumers.

Only two of these were available from several manufacturers under a generic name.

Approximately 50 percent of the total cost to patients was represented by the top 53 drugs, which also represented 53 percent of the total number of prescriptions and 49 percent of the total acquisition cost to retailers. Among these were 30 drugs which could be obtained only under a brand name from a single supplier, 16 which were

dispensed under a brand name although a chemical equivalent was available, and 7 which were dispensed under generic name.

*Therapeutic Category.* Cardiovascular preparations–including vasodilators, digitalis and its congeners, and hypotensive drugs–accounted for 38.9 million, or 22 percent, of the total prescriptions, and $157.8 million, or 23 percent, of the total retail cost to consumers.

Tranquilizers, with 16.9 million prescriptions at a total cost of $78.9 million, rated second, followed by diuretics, with 16.0 million prescriptions at $62.6 million; and sedatives, with 15.1 million prescriptions at $32.3 million.

These four categories together represented about one-half of all prescriptions for products in the MDL, and of the total cost to patients.

Antibiotics ranked fifth, including 13 million prescriptions at a retail cost of $64.3 million.

*Diagnostic Category.* About 66.2 million, or 38 percent, of the total prescriptions, at a cost of $244.3 million, or 36 percent, of the total retail cost, were used for the treatment of heart disease and hypertension.

An additional 17.3 million prescriptions, at a retail cost of $65.4 million, were applied for the control of arthritis and rheumatism.

About 11.6 million prescriptions, at a cost of $47.4 million, were dispensed for the treatment of mental and nervous conditions.

Together these groups accounted for 95.1 million, or 54 percent, of the total MDL prescriptions, and $357 million, or 52 percent, of the total cost to consumers.

*Maintenance Therapy.* A sizeable proportion of out-of-hospital drugs prescribed for the elderly are so-called long-term maintenance drugs, used primarily for the control of chronic diseases. Few of these–at least at the present state of knowledge–can be cured, but in many instances appropriate drug therapy will enable the patient to live a reasonably comfortable and productive life.

Among the 409 drugs in the MDL, 70 were prescribed for 30 to 59 days during the year, 42 of them for 60 to 89 days, and 78 of them for 90 days or more.

These last 78 accounted for only about 20 percent of all MDL products, but they represented 59.6 million, or 34 percent, of all MDL prescriptions, and $242 million, or 35 percent, of total costs to the consumer. More than half of them were for the control of cardiovascular disease.

***From the foregoing, the Task Force finds that the requirements for appropriate prescription drug therapy by the elderly are very great–far greater, in fact, than those of any other group–and that many elderly men and women are now unable to meet these needs with their limited incomes, savings, or present insurance coverage. Their inability to afford the drugs they require may well be reflected in needless sickness and disability, unemployability, and costly hospitalization which could have been prevented by adequate out-of-hospital treatment.***

With steadily increasing prescription expenditures, this problem is destined to become increasingly serious.

We recognize that Medicare provides the great majority of the elderly with substantial protection covering the drugs they receive while they are inpatients in hospitals and extended care facilities, and that they therefore have adequate protection against the drug expenses associated with their most serious acute illnesses, but they have a need for improved protection against the cost of drugs they use when they are not hospital or extended care inpatients, and especially against those costs associated with the serious chronic conditions which afflict them.

***We therefore find that, in order to improve the access of the elderly to high quality health care, and to protect them where possible against high drug expenses which they may be unable to meet, there is need for an out-of-hospital drug insurance program under Medicare.***

## *CHAPTER 2*
## *THE DRUG MAKERS*

Since World War II, the American drug industry has risen to a position of worldwide leadership in drug research, development, production, and distribution.

It is now the center of intense controversy, and heavy criticism has been leveled at both its motives and its methods. At the same time, it has been vigorously defended, with detailed descriptions of its many contributions to the health of mankind, and with insistence on the reasonableness of its prices and profits.

### *The Industry*

Total drug sales–prescription and nonprescription drugs alike–have increased substantially in the last decade, rising from nearly $3 billion in 1957 to about $5 billion in 1967 at the manufacturer's level. Prescription drugs accounted for about two-thirds of this volume.

Foreign drug sales by American companies exceeded a billion dollars in 1967.

Approximately 95 percent of the prescription drug sales were made by the 136 member companies that comprise the Pharmaceutical Manufacturers Association (PMA). Members of the PMA produce and sell both brand-name and generic-name products. Just as they account for the overwhelming proportion of sales, they conduct essentially all of the industry's research, they control the overwhelming proportion of drug patents, they conduct the most vigorous promotion of their products, they compete vigorously–usually on the basis of innovation and quality and rarely on the basis of price–for the favor of the medical profession, and they achieve the industry's highest rates of profit.

The remaining five percent of the Nation's prescription drugs are manufactured by many hundreds of companies, and are sold under both brand and generic names. The total number of such firms is believed to be more than 700. They control few drug patents, do little or no research, compete on the market on the basis of both quality and price, conduct only minimal promotion of their products, and achieve relatively low rates of profit.

### *Research and Development*

Various Federal agencies support drug-related research and development at the rate of more than $100 million a year. In addition, other studies included in the Federally-supported biomedical research program may be expected to have eventual implications for drug research and development.

The drug industry's research and development program is now nearly $500 million a year, almost all conducted by about 70 of the PMA members.

The industry's research effort has been noteworthy in many respects–

- New drugs developed through research have given physicians remarkable weapons for the improved treatment of infections, metabolic disorders, arthritis, heart disease, high blood pressure, and a host of other crippling or deadly diseases.

- Based on percentage of sales, the drug industry's investment in research is about three times greater than that of any other major industry.
- The number of new products has been impressive. For example, between 1957 and 1968, 311 products introduced on the market were described as important new single entities. They represented about 15 percent of the 2,131 new prescription drug products introduced during that period. Also included were 1,440 products containing two or more older drugs in a new combination, and 380 drugs which were essentially duplicates or minor modifications of products already in use.
- The annual number of important new entities, those which represent significant advances, reached a peak in 1959–three years before the Kefauver-Harris Drug Amendments of 1962–and decreased steadily until 1967, when the number started to rise again.

Also impressive is the vigor and frequency with which industry spokesmen have said that any government interference in their operations may force them to reduce their research programs.

The Task Force is convinced that the directions and quality of some industry research programs deserve careful consideration.

We have noted the serious and increasing concern expressed by practicing physicians, medical educators, pharmacologists, and economists–and even some industry leaders–at the number of molecular modifications of older drugs introduced each year. Some of these modifications undoubtedly represent significant advances, but most appear to be so called ''me-too'' drugs–substances which are not significantly different from other drugs, nor significantly better, and represent little or no improvement in therapy, but which are sufficiently manipulated in chemical structure to win a patent.

We have noted the comparable concern expressed at the number of new fixed combinations of old drugs introduced each year. Although these combinations may offer some convenience to elderly patients in particular, clinicians and pharmacologists have cautioned that they also involve obvious hazards and combine drugs in a ''locked-in'' proportion which may or may not fill the needs of individual patients.

The numbers of duplicative and combination drug products introduced in recent years have been decreasing, but they still represent the great majority of all so-called new drugs.

It is evident that these duplicative products, along with combination

products, are used widely by some physicians, perhaps on the basis of the industry's exceedingly effective marketing and promotion activities. For example, of the 409 most frequently dispensed drugs for the elderly included in the Task Force Master Drug List, about 190 are combination products, and a substantial number of the others could be classed as duplicative or ''me-too'' products. But it is also evident that the need for this overabundance of drug products has not been convincing to some medical experts. Thus, in many of the Nation's leading hospitals, when expert physicians have served on pharmacy and therapeutics committees to select the drugs needed for both inpatient and outpatient therapy, they have generally found many if not most of these duplicative drugs and combinations to be unnecessary. These products have been found generally unnecessary by physicians providing medical care to the armed forces. They have been found generally unnecessary by leading clinical pharmacologists.

If these items were offered at prices substantially lower than the products they duplicate, they would provide at least an economic advantage, but in most instances they are introduced at the same or even higher prices.

The development of such duplicative drugs or combination products cannot be considered an inexpensive fringe benefit. Each requires laboratory research, clinical trials and the accumulation of sufficient data to demonstrate to the Food and Drug Administration that the new product–although it may not represent any significant therapeutic advance–is at least safe and efficacious.

> ***Since important new chemical entities represent only a fraction–perhaps 10 to 25 percent–of all new products introduced each year, and the remainder consists merely of minor modifications or combination products, then the Task Force finds that much of the drug industry's research and development activities would appear to provide only minor contributions to medical progress.***
>
> ***We likewise find that to the extent the industry directs a share of its research program to duplicative, noncontributory products, there is a waste of skilled research manpower and research facilities, a waste of clinical facilities needed to test the products, a further confusing proliferation of drug products which are promoted to physicians, and a further burden on the patient or taxpayer who, in the long run, must pay the costs.***

A solution to this problem requires joint efforts on the parts of industry and the Federal Government.

### *Quality Control*

Any company, large or small, brand-name or generic-name producer, can institute and maintain an effective quality control program, and most companies have apparently done so. The cost of such a program has been estimated to be about 2.4 percent of sales for a large company, but may be somewhat more for a smaller firm.

On the other hand, not all companies have maintained adequate quality control, and their products have had to be recalled–either voluntarily or by government order–for such defects as mislabeling, subpotency, or contamination. These recalls have involved both large and small firms, and both brand-name and generic-name products.

Several hundred such violations are reported each year. Investigations have often indicated that these are related to the failure of a manufacturer to comply with what are known as Good Manufacturing Practices, including such factors as plant sanitation, personnel surveillance, equipment maintenance, raw material standards, record keeping, and quality checks at every appropriate stage of manufacture and packaging.

The Task Force believes that this situation may be substantially improved by the intensified inspection program introduced in 1968 by the Food and Drug Administration. At the same time, it believes that further study is warranted of the alternative proposal that a registration and licensing system be established under which no drug product would be permitted in interstate commerce unless produced under quality standards set by the Secretary of Health, Education, and Welfare.

### *Marketing*

For those major companies which have presented any data, marketing expenses–including particularly those for advertising and promotion–represent from about 15 to 35 percent of sales. Such expenses for generic-name products appear to be substantially lower than those for brand-name products.

Industry spokesmen have claimed that marketing is an accepted part of any business activity; that their marketing costs are reasonable; and that their marketing efforts–including advertising, direct mailings, and personal visits by detail men to physicians–are primarily educational

in nature. They have claimed that the promotional aspects of drug marketing are a mark of the intense competition in the industry.

On the other hand, critics have asserted that intensive promotional efforts may be acceptable to sell such products as detergents, beer and used automobiles, but not for such vital necessities as prescription drugs; that the expenses for drug marketing are excessive and add needlessly to the cost of prescriptions; that prescription drug advertising and other promotion has reached the proportions of supersaturation, and that some has been–at least until recent regulations were established by the Food and Drug Administration–inaccurate, unscientific and biased.

It appears evident to the Task Force that drug promotional activities are related to the particular type of competition which unquestionably exists in the prescription drug industry–among others, an intense competition between companies, with the promise of a greater share of a relatively limited market and richer profits for the successful competitor–but that these activities have little to do with normal price competition in the retail marketplace, with the promise of eventual price savings to the consumer.

*The Strategy of Names*. Intimately related to marketing, and the competition between brand and generic products, is the subject of brand and generic names.

In the past, whether fortuitously or by design, most generic names–though certainly not all of them–have been relatively long, complicated and difficult to pronounce and remember.

During the past year, this situation has improved somewhat as the result of new policies established by the U.S. Adopted Names Council, but more improvement is needed.

The Task Force commends the Council for its efforts toward simplifying generic names and urges that these efforts be continued and strengthened.

*Advertising and Promotion*. Included among the promotional activities of some major prescription drug companies have been the support of scientific or medical conferences or symposia totally unrelated to any commercial product; the publication of educational materials for the public on such subjects as prevention of narcotic and drug abuse, immunization campaigns, and school health; the establishment of scholarships and fellowships, especially for the benefit of underdeveloped

countries; and the no-strings-attached support of some scientific and medical societies.

These and similar activities are held in high esteem by many in the scientific and medical community, and are viewed as significant contributions to the improvement of public health.

Also included among promotional activities is the drug advertising in medical journals, direct mailings, throw-away publications, and others which has long since reached astounding proportions. It is estimated that the major drug companies together spent in 1968 some $4,500 per physician annually to reach each of the nearly 200,000 physicians who represent the target audience–those who will decide for which drug product their patients should pay.

Significantly, this advertising rarely if ever mentions price.

Unquestionably, much of this material is accurate and educational. The frequency of biased, inaccurate drug advertising has apparently been reduced since the enforcement of new advertising regulations by the Food and Drug Administration began in 1967. But the overall value of such advertising volume continues to be seriously questioned.

Similarly, the potential impact of these large advertising expenditures on the editorial policies of the journals which are supported in large part by drug advertisements appears to deserve careful study.

*Detail Men*. Major brand-name manufacturers–and a few generic-name companies–employ about 20,000 representatives to call on physicians, hospital, and pharmacists, and provide information on their products.

Whether such activities may be described as primarily promotional or primarily educational is difficult to determine. It is doubtful, however, that physicians can expect such detail men to give invariably unprejudiced and objective advice.

Significantly, the presentations of detail men rarely include mention of price.

*Free Samples*. Free drug samples have customarily been distributed to physicians without request to induce them to try a product and test its advantages on their own patients. But few physicians are able to undertake any serious trials of this nature. Furthermore, if a physician does try a drug, in most instances he can do so with only a very few patients; the possibility that such a limited study can serve as a basis for a scientific judgment seems to be small.

Free drug samples have made it possible for physicians and

hospitals to supply drugs at no cost to some indigent patients. This need, however, has been modified by the advent of Medicaid and other programs under which Federal and State welfare funds may be used to provide drugs to eligible patients.

It has been reported that free samples have been involved in accidental poisonings, drug abuse, and black market activities.

Some major drug manufacturers have reacted to this problem by distributing free samples only to those prescribers who have specifically requested them. It appears that further steps in this direction call for joint efforts by the industry and the Federal Government.

### *Industry Prices*

Few aspects of the drug industry are more confused–or more confusing–than its pricing structure. Ostensibly, wholesale prices are listed in company catalogs and price lists, but these generally represent maximum prices. They serve merely as an umbrella beneath which actual prices are set by quantity discounts, hospital discounts, government discounts, two-for-the-price-of-one deals, rebates, and other special arrangements.

With many Federal, State and private drug programs now using reimbursement formulas supposedly based on product costs to the vendor, there is need for developing an efficient system to ascertain actual acquisition costs. This calls for cooperation among manufacturers, wholesalers, vendors, insurance companies, and governmental agencies.

*Price Indices.* Particular confusion has resulted from the comparison of various indices intended to indicate the trend of drug costs.

From the Consumer Price Index of the Bureau of Labor Statistics, it seems obvious that retail drug prices have been decreasing steadily since about 1958.

From three independent surveys, it seems equally obvious that these prices have been increasing during the same period.

The disparity is based on the fact that the indices are measuring different things.

The BLS index is aimed at measuring the change in a relatively fixed ‘‘market basket’’ of about a dozen arbitrarily selected drug products. During the past decade, the prices of these items have, on the average, decreased. The items selected for the ‘‘basket,’’ however, do not accurately and fully represent the most widely used drugs, and

they do not reflect the changes in consumer expenditures which constantly occur when new, presumably better, and certainly more costly products are introduced on the market and replace less costly products.

On the other hand, the independent, surveys are not concerned with the price changes of any individual drug products, but instead are aimed at determining the average price of all the prescriptions which people do purchase. All three of these surveys show a definite upward trend in the average cost of these prescriptions, but they do not agree in the extent of increase because of different sampling methods.

Thus, there is need for information on actual drug costs, expenses and utilization by the elderly and other groups.

***Accordingly, we recommend that the Department of Health, Education, and Welfare should conduct a continuing survey of drug costs, average prescription prices, and drug use.***

*Hospital and Government Discounts*. Many drug manufacturers customarily offer their products to hospitals at prices substantially lower than those available to community pharmacists. The savings are not necessarily reflected in lower drug prices to hospital patients.

To a considerable extent, these hospital discounts represent a subsidy to hospital patients–or, more often, to the hospitals themselves–at the expense of nonhospitalized patients.

Spokesmen for some pharmacy associations have urged that wholesale prices to hospital pharmacies and community pharmacies be kept at the same level–a move which would lower prices moderately to community pharmacies, but raise them substantially to hospital pharmacies. Hospital spokesmen have declared any such action would raise hospital per diem rates still higher.

Similar differences are apparent between the prices of drugs sold to community pharmacies and those sold to Federal and State agencies.

The Task Force believes that the substantial differences in the prices at which the same drug products are offered to community pharmacies and to hospitals and governmental agencies, respectively, deserve further examination.

*Foreign Prices*. Many American companies offer their products for sale in foreign countries at prices substantially below those available in the United States primarily to meet price competition which does not generally exist in this country.

During the past few years, there has been mounting insistence that these companies should price their products essentially the same in all countries.

The drug companies have countered that any increase in their foreign prices would drive them out of the foreign markets, not only reducing their earnings but upsetting still further this country's unfavorable balance of trade. On the other hand, any attempt to reduce American prices to the level of prices on foreign markets could be catastrophic to their total financial structure.

We believe that further study is required on the different prices at which drug products are offered to American and foreign purchasers.

***Patents, Trademarks and Competition***

In the case of most commodities, rival companies compete vigorously on the open market on the basis of both quality and price, with the consumer having the right to make the final judgment. In most instances, the results have been steadily increasing quality and decreasing price.

In the case of drugs, there are distinct differences. The competition is based almost entirely on real or presumed therapeutic advantages. The patient, who must pay for the drug, rarely has any voice in its selection. The decision on which product the patient must buy is made by the physician. Although moderate or even enormous price differences may exist between products of comparable quality, this is seldom brought to the physician's attention.

Some have attempted to justify this situation by describing the physician as the patient's expert purchasing agent. In the view of the Task Force, this concept is not valid; in most situations, a purchasing agent who purchased without consideration of both quality and price would be unworthy of trust.

In what has been described as this ''new competition'' in the drug business, patents and trademarks have played key roles.

On the one hand, industry supporters have insisted that the present patent and trademark system makes possible the incentives and rewards that are essential for the industry's large research and development effort, the flow of new products to which it leads, the subsequent benefit to health, and the ready identification of brand-name products.

On the other, it has been asserted that drug patents, combined with multi-million-dollar drug advertising campaigns, can keep new or

small companies out of the high-profit circle, and effectively stifle price competition in the marketplace.

Various proposals to modify the patent system have been considered by the Task Force.

*Abolition of Drug Patents*. Removal of all patent protection from new drugs, it appears, would be a destructive move. Virtually all the important new drugs of recent years have come from countries providing patent protection. Few, if any, have come from Eastern European nations which offer little or no patent protection. Several important drugs have originated in Italy, which does not provide patent protection, but these have been quickly patented in foreign countries.

*Restricted Patent Life*. It has been estimated that a company will usually recoup all its research and development costs of a product within about three years after it reaches the market. Accordingly, it has been proposed that the patent on a drug should be reduced from the present period of 17 years to a much briefer period–such as 10 years, 7 years, or even 5 years.

It has been shown, however, that requirements to establish the safety and efficacy of a new drug may take many years of effort–perhaps as many as seven years. Where such testing continues after a patent is issued, the period of actual patent protection may be less than the statutory 17-year period.

*Co-Terminal Patents and Trademarks*. It has also been recommended that the patent life on a drug be maintained at the present 17 years, but that exclusive rights to the trademark should last no longer than the patent. Thus, at the end of the 17-year period, any qualified manufacturer would be free to market the drug under its original trademark or brand name.

*Generic Name Only.* A related proposal is that new drugs should be marketed only under a generic name–exclusively by the inventor until the patent expired, and then by any qualified manufacturer who desired to produce it. Used with the generic name would be the name of the manufacturer, to identify the source of the product. This would clearly tend to minimize the confusing multiplicity and complexity of names put before physicians and would better identify the nature of the drug.

*Compulsory Licensing*. Unlike the United States, many countries have provisions under which the government may require the patent holder to license other manufacturers through a suitable royalty system. These provisions have rarely been enforced, perhaps because

realistic price competition exists in the marketplace and lower prices may be invoked through negotiations.

Proponents of such legislation in this country have argued that if licensing were required after the first three years of a product's market life–i.e., after major recovery of research and development costs–other firms could enter that product market by paying royalties, and price competition might then occur among these rivals. Beneficial results to consumers would be possible only for those products with a commercial life longer than three years. For such products, the patent holder would continue to earn an innovator's profits, though perhaps at lower rates than before, and consumers possibly could purchase prescriptions at lower price levels.

*Make-or-Sell Licensing*. As yet another approach, it has been proposed that the patent holder should not be permitted to monopolize both the manufacture, and the sale of a new drug, but should be required to license either other producers or other sellers.

We note that these and other proposals to amend patent and trademark laws on drugs have been considered in the United States and other countries, and believe further study is necessary.

***Release of Technical Information***

As part of the New Drug Application procedure of the Food and Drug Administration, the manufacturer of a new drug product is required to submit a voluminous quantity of clinical and technical information, including data on ingredients and methods of production.

The FDA had held that the New Drug Application and the technical information included in it are the property of the applicant, and cannot be released–except with the applicant's consent–even after the patent has expired.

Whether or not this policy is appropriate and in the public interest has been questioned. Recently Dr. James L. Goddard, then Commissioner of the Food and Drug Administration, testified on this matter:

> ". . . I think properly that the question should be discussed by Congress in terms of the scientific and business community involved. Congress should get down to the issues involved here and see whether or not the interest of the public at large might better be served by a public policy which permitted disclosure of the clinical [and] the scientific information incorporated in New Drug Applications."

### *Profits and Risks*

In a free enterprise system, it is obvious that a company must make a profit. Unless it achieves this primary objective, it cannot stay in business.

Ample evidence is available to demonstrate that the drug industry has been able to stay in business. It has maintained an annual profit rate based on net worth which is substantially above that of the average of major American industries.

- One study of 41 industries has shown that, between 1956 and 1966, the drug industry never ranked lower than third on the basis of after-tax income as a percentage of net worth. In six of those years, it ranked in first place.
- Another study showed that, among 31 major industries, drug makers have averaged an 18.1 percent return on capital, as compared with 9.7 percent for the whole group.

A similar high rate of profit for the drug industry is indicated on the basis of profits calculated as a percentage of sales.

Spokesmen for the drug industry have agreed that its profitability is above average. They say, however, that this high rate is necessitated by the high degree of risk in the industry, and the need to attract the capital to finance further growth.

The Task Force has been unable to find sufficient evidence to support the concept of the drug industry as a particularly risky enterprise.

There is abundant evidence that the development of an individual drug may be associated with a high degree of risk, and that any such development is an economic as well as a scientific gamble.

There is, however, no evidence that this kind of risk characterizes a typical major drug company with a substantial line of drug products. When such a company undergoes a painful loss in this kind of a gamble, the record would seem to show, it generally covers it by substantial profits on other drugs.

The record would also tend to show that–at least during the past 20 years–losses of this nature have driven few if any major pharmaceutical manufacturers into serious financial straits.

In recent years, some major American drug manufacturers have diversified their operations by moving into other operations. In some instances, this has been described as an attempt to minimize risks. At the same time, however, it is apparent that other companies are diversifying their operations by moving into the drug field.

The Chief Economist of the Federal Trade Commission has testified that, on the basis of advice given by investment analysts, there is no reason to conclude that the drug industry is a uniquely risky industry. In fact, it appears that large drug companies should have little difficulty obtaining adequate capital for growth should they choose to go into the market for it. Actually, however, their earnings are large enough to preclude the frequent need for equity capital.

If new Federal regulations concerning drug safety, drug efficacy, and drug advertising have had any significant effect in reducing drug profits, this is not evident in recent drug company profit statements.

***The "Reasonableness" of Drug Prices***

Whether prescription drug prices set by the major manufacturers are "too high," "reasonable," or "too low" is obviously a problem which cannot be resolved to the mutual satisfaction of all manufacturers and all consumers.

It appears, however, that current drug prices at the manufacturer's level are marked by these characteristics:

- They reflect research and development costs which are relatively high in comparison with other industries, and which include a substantial degree of effort yielding only duplicative or "me-too" drugs and combination products that contribute little to the improvement of health care.
- They reflect promotion efforts which are high and are directed primarily to physicians.
- They reflect a high degree of competition based essentially on quality and innovation, rather than the normal competition based on quality, innovation, and price.

***We find, therefore, that the exceptionally high rate of profit which generally marks the drug industry is not accompanied by any peculiar degree of risk, or by any unique difficulties in obtaining growth capital, and that industry profits have not been significantly reduced by new governmental regulations concerning drug safety, drug efficacy, or drug advertising.***

It is also evident from this study that there are certain problem areas which call for cooperative study and action by the drug industry, private groups, and the Federal Government.

***Accordingly, the Task Force recommends that the Secretary of Health, Education, and Welfare should call one or more conferences with representatives of the drug industry, pharmacy, clinical medicine, and consumer groups to consider–***

***a. Provision of incentives to the drug industry to invest more research effort in products representing significant improvements to therapy and less in duplicative, noncontributory drug products and combinations.***
***b. Development of a registration and licensing system under which no drug product would be permitted in interstate commerce unless produced under quality control standards set by the Secretary of Health, Education, and Welfare.***
***c. Limitation of free drug samples, by industry agreement or legislation, to those specifically requested by prescribers.***
***d. Development of more effective methods for ascertaining actual acquisition costs of prescription drugs.***

Similarly, it is evident that certain other areas of concern require detailed analysis by appropriate agencies of the Federal Government.

***The Task Force therefore recommends that the Secretary of Health, Education, and Welfare should call for a joint study by the Department of Health, Education, and Welfare, the Department of Commerce, the Department of Justice, the Federal Trade Commission, and other Federal agencies to consider–***

***a. The substantial differences in the prices at which drug products are offered to community pharmacies and to hospitals and government agencies.***
***b. The substantial differences in the prices at which drug products are offered to American and foreign purchasers.***
***c. Revision of patent and trademark laws on prescription drugs.***

## *CHAPTER 3*
## *THE DRUG DISTRIBUTORS*

Between the manufacturers who make drugs and the patients who purchase them is a large, complex distribution network.

Included in this network are the major drug vendors–independent pharmacies, chain drugstores, prescription pharmacies, mail-order pharmacies, hospital pharmacies, dispensing physicians, and others. Considered with them in this section are the drug wholesalers.

Of the average prescription drug dollar paid by the consumer, about 50 cents is now taken by the manufacturer, 10 cents by the wholesaler, and 40 cents by the retailer.

On the basis of available data, it appears that profits before taxes for independent drugstores and other community pharmacies represent an average of about 5 percent of sales, or about 21 percent of net worth.

For hospital pharmacies, the average outpatient prescription price probably approximates the national community pharmacy average prescription price, even though drug costs and operating expenses may be appreciably lower, and no income taxes may be involved. Accordingly, the profit ratios for such hospital pharmacies may be substantially higher.

During the past three decades, the operations of the drug distribution system have undergone significant changes. For example, before World War II, most of the drug products handled were in bulk form, and were compounded into tablets, capsules, powders, solutions or other dosage forms by the pharmacist. Now about 95 percent are furnished by the manufacturer in final dosage form, ready for consumption.

Formerly, wholesalers handled the overwhelming proportion of drug products. Now, with manufacturers tending to sell directly to hospitals and the larger independent pharmacies and chains, the wholesalers handle only about 48 percent of the dollar volume of the market.

In the years to come, other changes in the number and nature of both wholesale and retail outlets will undoubtedly occur as the result of continuing economic pressures, health manpower shortages, the expansion of new types of careers in pharmacy, and the introduction of innovations enabling drug distributors to respond more effectively and efficiently to the health needs of patients.

A nationwide drug program under Medicare would inevitably provide new challenges and new opportunities. Certain aspects of such a program–notably the methods of reimbursement–deserve particular consideration.

***Percentage Markup versus Dispensing Fee***

Traditionally, most pharmacists have determined the retail price of a prescription drug by adding to the wholesale or acquisition cost a percentage of this cost–for example, 65 to 100 percent or more. Such a system is known as the percentage markup, or margin, method. This approach is currently supported by the National Association of Retail Druggists.

It is obvious that this method may serve as an inducement to a pharmacist to dispense the more expensive brand of a prescribed drug, if he has any choice in selecting the brand. To a considerable extent, it appears to lay a heavy burden upon the patient unfortunate enough to require expensive medication, and such an individual actually subsidizes the patient who requires less costly prescriptions.

More recently, some pharmacists have advocated the use of a dispensing fee which is the same regardless of the acquisition cost–an approach which has been endorsed particularly by the American Pharmaceutical Association. This method is based on the concept that dispensing activities represent a professional service that is generally unrelated to the acquisition cost of the drug, since the pharmacist usually performs the same service whether the medication costs 10 cents or $10.

As one authority has stated:

> ''In applying the fee concept to a pharmacy practice, a pharmacist makes two assumptions which are the philosophic principles underlying its use. *First*, the pharmacist is a health specialist by virtue of his knowledge, education, and training, and dispensing prescription medication is a pharmaceutical service. For this act, he receives a fee . . . *Second*, the services a pharmacist provides in dispensing prescriptions is, in general, the same for all prescriptions, and the cost of providing this service remains relatively constant from one prescription to the next.''

The use of the dispensing fee approach reduces the relative costs of high-priced medications, while increasing the costs of low-priced drugs, but the system appears to be more equitable since it eliminates the subsidization of some patients by others.

From the point of view of the vendor, employment of a fixed dispensing fee system means that physicians may attempt to help some

of their patients needing long-term maintenance drugs by prescribing large quantities of drugs at one time, carrying only a single dispensing fee, rather than an original small prescription plus many small refills, each carrying a dispensing fee.

### *Dispensing Physicians*

A dispensing physician is considered to be one who stocks a more-or-less complete line of drug products in his office, and sells these directly to his patient instead of writing a prescription for the patient to take to a pharmacy. The charges he makes may be essentially the same as those set by pharmacies in his community–or substantially higher or lower. (Not included in this category are physicians who administer a drug to a patient–usually in the course of a home or office visit–and include the cost as part of their fee for professional medical services.)

Some physicians find it necessary to sell drugs directly to patients in this way in emergencies, or because they practice in isolated areas in which no regular pharmacy services are available, but such situations would seem to be relatively uncommon.

In view of the acute shortage of physicians, the heavy demands already placed upon them to use the professional skills which only they possess, the possible conflict of interest which may be involved, and the propriety of burdening them with functions which can be performed at least as well by others, the Task Force believes that the role of dispensing physicians in an out-of-hospital drug program under Medicare warrants further study.

### *Government Pharmacies*

It has been proposed that existing Veterans Administration and other Federal hospital pharmacies be used to dispense prescription drugs to beneficiaries of both the Medicare and Medicaid programs, either in person or by mail. Such an approach would presumably offer substantial savings, but the limited number and the location of these Federal hospital pharmacies would make it impractical for them in most cases to dispense except by mail, and would offer only limited pharmacist-patient relationships.

### *Physician-Owned Pharmacies*

The ethical status of physician-owned pharmacies has recently been under consideration by the American Medical Association and other groups.

On the one hand, it has been held that such pharmacies offer particular convenience to patients, that they can often purchase drugs from manufacturers or wholesalers at prices which are not available to many community pharmacists, that they can maintain small inventories, and that they are more likely than community pharmacies to ensure that patients will receive the proper medication.

Although low inventories and relatively low acquisition costs could result in lower drug prices to patients, there is no evidence that the average prescription prices set by physician-owned pharmacies are any lower than those set by other pharmacies in the community. Further, there is no evidence that physician-owned pharmacies are any more or less likely to dispense improper medication.

In addition, it has been held that patients treated by a physician who both prescribes drugs and has a financial interest in the pharmacy which dispenses the drugs are clearly a captive audience, with no freedom of choice on where they will have their prescriptions filled. With the physician occupying a dual role as prescriber and dispenser, there is an obvious conflict of interest, with an evident risk of excessive prescribing. Further, a physician-dominated pharmacist may not exercise needed objective review of what may appear to him to be prescription errors.

Accordingly, the Task Force believes that the role of physician-owned pharmacies in any Medicare program warrants further study.

### *Physician-Owned Repackaging Companies*

A drug-repackaging company is one which purchases a drug product from a manufacturer, usually in large quantities at a relatively low price, and then repackages it under its own brand name–and at its own price.

If such a firm is controlled by one or more physicians who set the price at an extraordinarily high level, and who prescribe its products under the repackaging company brand name–thus requiring the pharmacist to dispense it–the profits to the company and its prescriber-owners can be extraordinarily rewarding. Under these conditions, the cost to the patient can also be extraordinarily and needlessly high.

The conflict of interests and the potential exploitation of patients in such a situation are so apparent that the American Medical Association in 1967 declared it to be unethical.

***Accordingly, the Task Force finds that products marketed by physician-owned repackaging companies should be considered***

***unacceptable for reimbursement in any Medicare program except in those instances in which the Secretary of Health, Education, and Welfare determines that the availability of products marketed by such companies is in the public interest.***

### *Prescription Price Information*

There is an obvious need for patients to be able to determine readily the prices charged by the various pharmacies in their community. This appears to be particularly important in the case of long-term maintenance drugs.

The Task Force recognizes the difficulties in making such information easily available. Many patients are not told which drug has been prescribed for them–or are unable to decipher the physician's prescription. In many States, laws or regulations forbid pharmacies to advertise; even without such rules, however, advertising current prices on many thousands of different drugs and dosage forms would pose formidable practical problems. Physicians, especially those in large cities, are likely to be unaware of the different prices which may be set at different pharmacies.

We also recognize that the retail price of the prescription includes not only the cost of the ingredients, but also in some instances the availability of home delivery and 24-hour-a-day operations, as well as the professional services of the pharmacist–and that different pharmacists may wish to place different values on such services.

We recognize that many or most patients may wish to select a pharmacy more on the basis of convenient location than on the basis of price.

Nevertheless, if the patient is to maintain the right to select a pharmacy, he also has a right to know the prices it charges and to compare these with other prices.

***We find there is a need for medical associations, pharmacy associations and consumer groups, working together at the local level, to develop mechanisms whereby patients may obtain information on local prescription prices, especially for long-term maintenance drugs.***

### *Prescription Label Information*

It is frequently necessary for a physician to determine the nature and amount of a prescription drug which a patient has been taking. In

some instances–as in the case of a suspected adverse drug reaction, or accidental or deliberate overdose–the rapid identification of a drug may be a matter of life and death.

***As a step in improving the quality of health care, the Task Force recommends that the Congress should enact legislation requiring that the containers of all dispensed prescription drugs be labeled with the identity, strength and quantity of the product, except where this is waived upon specific orders of the prescriber.***

### *Prepackaging*

Prepackage dispensing is now being utilized for a variety of drugs in Europe, and for such products as oral contraceptives in the United States. In certain cases, this technique appears to offer significant advantages.

***To promote efficiency and minimize errors, the Task Force recommends that encouragement should be given to the wider use of prepackage dispensing, in which manufacturers prepare and pharmacists dispense tablets and capsules in precounted form, in sealed, prelabeled containers, and in such numbers as conform to those most frequently prescribed by physicians.***

### *The New Role of Pharmacy*

The pharmacy profession currently faces a dilemma which is partly though not entirely of its own making.

Many other aspects of health care–the practice of medicine and surgery, hospital operations, and particularly drug manufacture–have developed and adopted new devices and techniques which have remarkably improved the provision of health services. In contrast, the number of important new methods introduced to enhance the efficiency of retail pharmacy operations, at least during the past two or three decades, has not been noteworthy.

***The Task Force recommends that the National Center for Health Services Research and Development should develop and support research to improve the efficiency and effectiveness of community and hospital pharmacy operations.***

The role of the pharmacist is viewed by many people as simply transferring pills from a large bottle to a small one–counting tablets,

typing labels, and calculating the price. Much of his time is seen as devoted to routine merchandising of cosmetics, shaving supplies, stationery and other commodities which have little or no relationship to health care.

This has raised doubts concerning the relevance of modern pharmacy education. As with other members of health professions, on the one hand, it would seem that much of the traditional education is not utilized, since a nonprofessional pharmacist–working under the supervision of a licensed pharmacist–can effectively perform many of the routine tasks of counting, labeling, and pricing. At the same time, many pharmacists are seeking a new role as a drug information specialist, and thus it would appear that their formal education has not taken this into account.

These problems regarding what the role of the pharmacist properly is–or should be–deserve careful consideration.

### *Pharmacist Aides*

Experience in numerous pharmacies–military and nonmilitary Federal installations, nongovernmental hospitals, and others–has demonstrated that individuals without formal pharmacy education can effectively undertake many of the routine activities of pharmacists, under the supervision of a licensed pharmacist.

Such activities offer the possibility of developing the career of pharmacist aide, comparable to the nursing aide, the orthopedic aide, the pediatric aide, the obstetrical aide, and similar paramedical positions.

### *Drug Information Specialists*

At the other end of the spectrum, it is also becoming evident that appropriately trained pharmacists may become new and vital members of the total health team by serving as drug information specialists.

Some community pharmacists are already providing such services. They do not prescribe, but they discuss practical details of drug administration, possible side-effects, and other facets of drug use with each patient to whom a prescription drug is dispensed. They maintain patient or family records which contain data on drugs which have been dispensed to each patient, allergic responses, and adverse reactions. They call to the attention of the physician any prescriptions which may have been written for the same patient by other physicians, and they refer to him any prescriptions which may involve drug-interaction, synergism, or similar effects.

Some hospitals–especially teaching institutions and those in major medical center complexes–are already using pharmacists as consultants on drug therapy. They serve not only as drug distributors, but also as sources of drug data for physicians, interns, residents, and nurses. They may participate in ward rounds with the staff, providing valuable drug information on both old and new drug products. Although they do not prescribe for patients, they enable the physicians who do prescribe to keep up more effectively with drug information.

While some pharmacists are already serving as drug information specialists, and others are probably competent to do so, not all pharmacists have adequate competency in this field. Some licensed pharmacists have received five or even six years of formal college training, but about 15 percent of those now in practice have received two years or less of formal pharmacy education, and nearly half of these have had courses lasting only about six months.

***Pharmacy Education***

The introduction of out-of-hospital prescription drug program under Medicare, with the probability of a very large increase in drug utilization, coming at a time when quality of health care, costs, and shortages in health manpower are all matters of great national concern, would present pharmacy with probably the most critical challenge it has faced in half a century.

The manner in which pharmacists, pharmacy associations, pharmacy schools, and the pertinent State pharmacy agencies respond to increasing demands for pharmaceutical services will unquestionably determine in large measure how the pharmacy profession will evolve during the years to come.

The Task Force commends the efforts of those pharmacy schools and State pharmacy associations which are already stressing continuing postgraduate education.

As a guide to additional responses which should be made, there is a clear need for a broad study of pharmacy education at all levels.

***The Task Force therefore recommends that the Bureau of Health Manpower should support–***

***a. The development of a pharmacist aide curriculum in junior colleges and other educational institutions.***

***b. The development of appropriate curricula in medical and pharmacy schools for training pharmacists to serve as drug information specialists on the health team.***

***c. A broad study of present and future requirements in pharmacy, adequacy of current pharmacy education, and the educational changes which must be made.***

### *Pharmacy Laws*

The present patchwork of State pharmacy laws, regulations, and codes of ethics obviously reflects attempts to cope with a variety of pharmacy problems on a piecemeal basis. Whether they are aimed at the protection of the public health or the prevention of competition–fair or unfair–it is not clear in all cases.

Many of these rules seem to have derived from periods of manpower excesses. They block efforts to cope with the present shortages of skilled manpower, the need for mobility to meet rapidly changing health needs, and the probable development of new careers in pharmacy.

***The Task Force recommends that the Health Services and Mental Health Administration should support studies of State laws, regulations, and codes, with priority given to the establishment of model State licensing laws, uniform reciprocity standards, and provisions for the utilization of pharmacy aides.***

## *CHAPTER 4*
## *THE DRUG PRESCRIBERS*

In the modern use of drugs, important roles are played by the drug researcher, the manufacturer, the distributor, the pharmacist, and the official who carries the legal responsibility for drug safety, efficacy and quality. But the most strategic role is that of the physician who prescribes the drug.

It is the physician who has major responsibility for the welfare of the patient.

It is the physician who is constantly faced with an awesome assortment of competitive and often duplicative products.

It is the physician who is the target of a barrage of advice, information, guidance, and promotion from detail men, advertisements, medical articles, pamphlets, bulletins, and throw-away journals.

And it is the physician who–with or without adequate training and competent advice–must make the decision on which drug or drugs to prescribe.

On his decision may well depend the health or even the life of his patient. On it will depend, at least in part, the quality, cost and effectiveness of any drug insurance program, governmental or nongovernmental. And on it will depend the economic well-being of a drug company.

***Rational Prescribing***

The appropriate selection of a drug–the right drug for the right patient, in the right amounts at the right times–is generally defined as rational prescribing, and any significant deviation is considered to be irrational prescribing.

Rational prescribing is obviously the result of judgments on many points–the safety and efficacy of the drug for the clinical problem at hand, the advantages or disadvantages of alternative forms of therapy, the most appropriate dosage form, the length and intensity of treatment, the possible side-effects or adverse reactions, and the possibility of drug interaction.

To these may be added judgments concerning relative costs.

Rational prescribing is clearly a major goal for the welfare of patients. It is likewise a major goal for any drug insurance program. Here, emphasis has been placed not directly on achieving rational prescribing but rather on preventing some of the more serious or costly forms of irrational prescribing. Among the latter are these:

- The use of drugs without demonstrated efficacy.
- The use of drugs with an inherent hazard not justified by the seriousness of the illness.
- The use of drugs in excessive amounts, or for excessive periods of time, or inadequate amounts for inadequate periods.
- The use of a costly duplicative or ‘‘me-too’’ product when an equally effective but less expensive drug is available.
- The use of a costly combination product when equally effective but less expensive drugs are available individually.
- The simultaneous use of two or more drugs without appropriate consideration of their possible interaction.
- Multiple prescribing, by one or several physicians for the same patient, of drugs which may be unnecessary, cumulative, interacting, or needlessly expensive.

We recognize that some patients may be receiving as many as 16 to 20 different drugs simultaneously, prescribed by either one or several different physicians, and that often physicians may not be aware that their patients are receiving drugs prescribed by others.

We see no reason to believe that any or all of these types of irrational prescribing can be effectively prevented–or that rational prescribing can be effectively induced–merely by rules and regulations. Instead, we believe the objective of rational prescribing can be reached most effectively through improving medical education–particularly in the area of clinical pharmacology–at both the undergraduate and postgraduate levels, supplying practicing physicians with objective data on which they can base their individual prescribing decisions, and supporting those in hospitals, clinics, medical societies and health insurance programs who are seeking to achieve rational prescribing by their fellow practitioners.

### *The Teaching of Pharmacology*

In most American medical schools, the principal course in pharmacology is given during the second year. Generally, this is the only formal exposure of the student to the subject.

The nature of pharmacology instruction has been a matter of much debate but little change. Although it is in reality a clinical as well as a basic science, it is taught primarily as a basic subject, with emphasis on the principles of drug action, a review of specific drug groups, examples of drug applications, and the broad fundamentals of prescription writing.

After the usual course in basic pharmacology, most medical students are given no formal training in the applied aspects of this field–in clinical pharmacology–but left to acquire what practical training they can absorb from a variety of courses in the several fields of clinical medicine.

Perhaps the most serious criticism of this informal exposure is that it fails to equip the soon-to-be physician with the essential scientific and critical attitudes towards the use of drugs and the evaluation of drug promotion–probably the most intensive promotion to which he will be subjected for the rest of his professional career.

The Task Force has noted that some medical schools have responded to such a deficiency by establishing courses in clinical pharmacology or pharmacotherapeutics. In these courses dealing with

the practical aspects of drug prescribing, emphasis is generally placed on such subjects as the design of comparative clinical drug trials, and the techniques of statistical analysis. Also included in some courses is the evaluation of drug advertising and promotional material, and the importance of drug costs.

Many who participate in these and related programs have received a major part of their training in the Section of Clinical Pharmacology in the National Heart Institute of the National Institutes of Health.

***The Task Force recommends that the Department of Health, Education, and Welfare should provide expanded support to medical schools, enabling them to include a course in clinical pharmacology as an integral part of the medical curriculum.***

***Postgraduate Education***

Upon entering private practice, the average physician, knowingly or unknowingly, becomes the key figure in drug marketing strategy.

- He must choose from a very large number of competitive and often duplicative products.
- He must deal with a very large amount of advice, biased or unbiased, from detail men, advertisements and other forms of promotion.
- Substantial efforts are made on his behalf by the drug industry and others to prevent any interference with his right to prescribe as he sees fit.
- Finally, it is assumed that he has the training, experience, and time to weigh the claims and available evidence, and thus to make the proper selection.

Everything, of course, hinges on the validity of this final assumption.

***We find that few practicing physicians seem inclined to voice any question of their competency in this field of therapeutic judgments. We also find, however, that the ability of an individual physician to make sound judgments under quite confusing conditions is now a matter of serious concern to leading clinicians, scientists, and medical educators.***

A distinguished pharmacologist, for example, has stated that lack of knowledge and sophistication in the proper use of drugs is perhaps the

greatest deficiency of the average physician today. Other medical leaders have pointed to the wide discrepancy in the prescribing habits of the average physician as compared to the prescribing methods recommended by panels of medical experts. Still others have commented on the continued use by the average physician of products which have been found unnecessary or unacceptable by specially qualified therapeutics committees in hospitals and clinics.

We note that the most widely used source of prescribing information is essentially a compilation of the most widely advertised drugs.

The responsibility for these and other deficiencies has been placed on various factors:

- Inadequate training in the clinical application of drug knowledge during the undergraduate medical curriculum.
- Inadequate sources of objective information on both drug properties and drug costs.
- Widespread reliance by prescribers for their continuing education upon the promotional materials distributed by drug manufacturers.
- The exceedingly rapid rate of introduction and obsolescence of prescription drug specialties.
- The limited time available to practicing physicians to examine, evaluate, and maintain currency with the claims for both old drugs and newly marketed products.
- The constant insistence on the idea that the average physician, without guidance from expert colleagues, does in fact possess the necessary ability to make scientifically sound judgments in this complicated field.

***Information Sources***

Several significant approaches have been attempted to cope with this problem. In the United States, a small number of independent publications–which do not publish advertising–seek to present objective evaluations of the efficacy, safety, rationality, and occasionally the costs of specific drugs. These have relatively limited circulation, but are highly esteemed by medical leaders.

Many American hospitals and clinics utilize pharmacy and therapeutics committees to develop formularies which serve as guidelines to the staff members of the institutions. These, too, appear to contribute significantly to rational prescribing.

Other approaches to the problem of communicating objective and updated drug information have been proposed. These include closed-circuit television programs originating in medical centers; the development of community pharmacy and therapeutics committees; the utilization of existing regional medical programs to sponsor continuing drug information programs; and the use of hospital pharmacies as drug information centers.

Several foreign drug programs–notably those in Great Britain, Australia, and New Zealand–provide all physicians with prescribing guidelines prepared by panels of independent medical experts. Such publications–frequently updated to meet changing conditions–have been widely accepted by the medical profession in those countries.

In the United States, much useful information on such factors as indications, contraindications, dosages, toxicity, and side effects is included in the so-called package inserts which must be enclosed with each container of drugs. While these are of considerable value, they are not seen often enough by the practicing physician to be of practical aid in prescribing.

From the foregoing, it is evident that many and perhaps most American physicians do not have adequate access to complete and objective information on prescription drugs. The existing compilations of data do not generally touch on relative costs, and they do not offer the ready comparison of generic-name products and their brand-name counterparts which would facilitate the rational and economic prescribing of drugs.

***In consideration of these factors, in view of the unfilled informational needs evident in this country, and as a major contribution to improving the quality of health care, the Task Force recommends that the Department of Health, Education, and Welfare should establish or support a publication providing objective, up-to-date information and guidelines on drug therapy, based on the expert advice of the medical community.***

***We recommend that the Department of Health, Education, and Welfare should support the efforts of county medical societies, pharmacy and therapeutics committees, medical foundations, and medical schools in taking the responsibility for providing continuing education to physicians on rational prescribing.***

The Bureau of Health Manpower, the Division of Regional Medical Programs, and the National Library of Medicine in particular should assign high priority to the support of such efforts.

***Finally, we recommend that the Secretary of Health, Education, and Welfare should be authorized to publish and distribute to all physicians, pharmacies, hospitals and other appropriate individuals and institutions a drug compendium listing all lawfully available prescription drugs, including such information as available dosage forms, clinical effects, indications and contraindications for use, and methods of administration, together with price information on each listed product, in readily accessible and comprehensive form.***

## *CHAPTER 5*
## *CURRENT AMERICAN AND FOREIGN PROGRAMS*

The provision of out-of-hospital prescription drugs through governmental or private insurance programs has been undertaken in one form or another for nearly a century. Many of these include techniques and approaches which deserve consideration in any out-of-hospital program that might be designed under Medicare.

Accordingly, the Task Force has examined a wide variety of ongoing programs–all of the major drug programs conducted by the Federal Government, a number of selected State programs, six of the leading private programs in this country, and the major programs in eleven foreign countries.

These programs are not directly comparable. In some foreign countries, for example, national economic and social structures lend themselves to controls and methods of operation which are probably not suitable in the United States. Certain aspects of military drug programs may not be adaptable for civilian programs. Other approaches utilized in private programs may be impractical for a government operation.

Nevertheless, a study of these diverse systems has proved to be illuminating. It has clearly indicated that out-of-hospital prescription drugs can be provided under programs that are medically acceptable and economically sound.

### *Federal Programs*

Through direct purchasing or reimbursement, the Federal Government is now concerned with the provision of prescription drugs through several major programs. As shown in Table 2, expenditures for drugs in these programs totaled about $514 million in fiscal year 1967.

*DOD Military Procurement.* The largest direct drug procurement program is that of the Department of Defense, with its responsibility for supplying about 3,000 military establishments in this country and overseas. A major characteristic of the DOD operation is its testing and inspection program to assure drug quality and the ability of the products to withstand prolonged exposure to climatic extremes. DOD sets its own drug specifications, maintains its own manufacturing plant inspectors, and operates its own testing program. Manufacturers must undergo stringent pre-award surveys of their facilities as well as testing of their products in DOD laboratories. After drug contracts are

TABLE 2. Estimated Federal Expenditures for Prescription Drugs, Fiscal Year 1967.

| | (Millions) |
|---|---|
| Direct Purchase | |
| Department of Defense | [a] $111.0 |
| Public Health Service | [b] 4.1 |
| Veterans Administration | [c] 39.5 |
| Federal Supply Schedule Contracts | [d] 6.2 |
| Total Direct | 160.8 |
| Reimbursement Programs | |
| CHAMPUS | 0.2 |
| VA Hometown Pharmacies | 2.9 |
| Public Health Service | 0.7 |
| Medicare In-Hospital | [e] 230.0 |
| Medicaid | [f] 119.4 |
| Total Reimbursement | 353.2 |
| Total, Federal Drug Expenditures | 514.0 |

[a] Includes $92.4 million purchased through Defense Supply Center, Philadelphia, Pa., and approximately $15.7 million purchased through Federal Supply Schedule Contracts; remainder purchased locally.
[b] Includes $1.3 million purchased through PHS Supply Service Center, Perry Point, Md., and $2.8 million from other sources including the Veterans Administration.
[c] Includes $14.6 million purchased through Federal Supply Schedule contracts administered by VA for General Services Administration.
[d] Includes purchases for miscellaneous Federal agencies.
[e] Includes $115.0 million for overhead drug expenses of hospitals and extended care facilities.
[f] Includes other Federally-supported State Public Assistance Programs; excludes $105.9 million, which was the State portion of the total drug program expenses.

awarded, both the plant facilities and the stored products are continuously spot-checked, and DOD actively solicits reports from military hospitals and physicians on drug quality, therapeutic efficacy, and adverse reactions.

About 240 of the 1,200 drugs currently stocked are purchased under generic name.

The DOD policy is to purchase drugs under contract from the lowest ''responsible bidder.'' It may buy foreign-made drugs where the acquisition cost is at least 50 percent less than ''responsible'' domestic bids. The same pre-award standards and continuing surveillance imposed on domestic firms are applied to foreign manufacturers with DOD contracts.

As a Federal purchasing agency, DOD may purchase patented products from unlicensed manufacturers.

*DOD Military Medicare*. Through its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), the Department of Defense provides out-of-hospital prescription drugs through hometown pharmacies to some 6.5 million eligible retired military personnel and military dependents. Various carriers are used for program administration.

Any pharmacy willing to meet CHAMPUS requirements may participate. The pharmacist is reimbursed for the acquisition cost of the drug plus a dispensing fee which has been set for each State.

Each eligible beneficiary must first meet a deductible requirement of $50 per year–or $100 per year per family–and pay a co-insurance charge of 20 or 25 percent, depending on beneficiary status.

No formulary requirements are involved.

The average prescription price in 1967 was reported to be about $4.15.

*Veterans Administration*. In 1967, the VA purchased drugs and biologicals costing $39.5 million for use in its own hospitals and pharmacies, and also procured drugs for other Federal agencies, such as the Public Health Service and the Office of Economic Opportunity.

Of the drugs used in VA pharmacies, about 86 percent are purchased from some 250 manufacturers who have been approved by on-site inspections. Each VA hospital has its own drug formulary of about 700 to 2,000 items developed by its own pharmacy and therapeutics committee, and tailored to fit the needs of the institution. The formularies are used as guidelines rather than prescribing limitations, since non-formulary drugs may also be prescribed.

Chemical equivalent drugs are widely used where available.

In addition, the VA Hometown Pharmacy Program provides out-of-hospital prescription drugs to eligible beneficiaries, generally those with service-connected disabilities. The hometown program, which involved an expenditure of $2.7 million in 1967, provides for reimbursement to pharmacies on the basis of acquisition cost plus a dispensing fee. No formulary is used in this program, and no deductible or co-payment is required.

*Office of Economic Opportunity.* Through its neighborhood Health Centers, OEO provides pharmaceutical services for about 800,000 persons in 44 programs.

Eligibility requirements vary but generally are based on a "poverty line" schedule, on Medicaid standards, or on other guidelines established by the community. Each center makes its own determination about the use of a formulary. No deductible or co-payment is required.

Several of the centers provide direct drug services in their own pharmacies, while the others provide for reimbursement to community pharmacies on the basis of acquisition cost plus a dispensing fee.

*Public Health Service.* In 1967, PHS expended more than $4 million for drugs for its own operations, and also purchased drugs for Civil Defense stockpiling.

Of the drugs procured for PHS activities, some were used by the National Institutes of Health and the National Institute of Mental Health, but most were dispensed through the Division of Direct Health Services–with 11 hospital and 14 clinic pharmacies–and the Division of Indian Health. The latter operates 51 hospitals with pharmacies, and contracts with about 200 community pharmacies that furnish prescription drugs to Indian beneficiaries.

Each PHS hospital has its own formulary, but exceptions are made for the provision of non-formulary drugs. Physicians who contract with PHS are not obliged to use the formularies.

Pharmacies participating under contract with the Division of Indian Health are required to dispense the least expensive drug products they have in stock which will meet the physician's requirements when a generic prescription is written. The price may not exceed the price to the general public.

No deductibles or co-insurance requirements are involved in any of the PHS out-of-hospital programs.

*Medicare.* Data from the Medicare program relating to the cost of

drugs provided to beneficiaries in hospitals and extended care facilities are not yet available. However, on the basis of recent studies of drug use in hospitals in general, it is estimated that in fiscal 1967 roughly $230 million was spent under Medicare for drugs, with about half of this amount representing product cost and the remainder the cost of dispensing and administration (see Table 2).

Under Medicare, in-hospital drugs must be listed in one of several official compendia or in a formulary established by the hospital's pharmacy and therapeutics committee. Medicare requires that drug charges to the government must be ''reasonable.''

*Public Assistance*. Under Medicaid and other public assistance programs with joint Federal-State support, an estimated $225.3 million was spent for prescription drugs in fiscal 1967, of which an estimated $119.4 million was paid by the Federal Government (Table 2). Federal-State vendor payments of $225.3 million (including about $43 million for in-hospital drugs) represented 9.6 percent of all medical care services provided in that year, and were made to hospitals, pharmacists, and other licensed vendors.

The Federal share of payments to vendors for drugs and drug services ranged from 50 to 83 percent, depending on the nature and extent of the program in each State, with an average of about 53 percent.

In such programs, no deductibles or co-payments are generally involved, although one non-Medicaid State program included a co-payment requirement but provided funds to the recipients to cover such payments.

Further details on these public assistance programs are presented in the following section.

### *State Programs*

Vendor drug programs for recipients of Medicaid and other public assistance funds are now operating in 38 States and Territories. The range in their utilization, costs, and benefits is very large.

Thus, among all eligible beneficiaries, the utilization rates in 1967 ranged from 26 percent in Missouri and Tennessee to 91 percent in New Hampshire and 99 percent in Rhode Island.

The average annual number of prescriptions per user ranged from about 10 in New Mexico to 46 in Indiana.

The average annual expenditure per user ranged from $39.35 in New Jersey to $148.95 in Florida, $155.67 in Nebraska, and $158.58 in Indiana.

The average cost per prescription ranged from $2.91 in Kentucky and $2.94 in Illinois to $4.74 in New Mexico.

Because of the diversity and complexity of the various State drug programs, the Task Force selected five for intensive study–California, because of its size; Louisiana and West Virginia, because of their approach in approving drugs used only for the treatment of specific diseases; Kentucky, because of its limited formulary; and Pennsylvania, because of its extensive formulary, which is used primarily as a guide to prescribing.

Other studies were conducted on the programs in Indiana, Nebraska, North Carolina, Oklahoma, and South Dakota.

In nearly all of these States, per capita drug costs and average prescription prices for program beneficiaries were higher than those for the total public. Whether this was the result of program abuse or of the greater health needs of those receiving public assistance cannot be readily determined.

There was no consistent pattern of vendor payments, with some states reimbursing on the basis of customary and usual charges, some on acquisition cost plus a percentage markup, some on acquisition cost plus a dispensing fee, and some using a combination of percentage markup plus dispensing fee. Several set dollar limits. There was no clearcut relationship between any of these methods and program costs.

Where acquisition cost was a factor in the reimbursing formula, this was generally presumed to be the listed wholesale price, although it is understood that this list price has little if any relationship to the actual acquisition cost. Few States made any efforts through spot audits to determine actual acquisition cost.

Administrative expenses have been estimated to average about 50 cents per prescription, with the lowest cost–about 20 cents–reported in Louisiana. Differences in estimating administrative costs, however, make it impossible to make exact comparisons.

Among the States studied, none was applying data processing techniques to the extent necessary for effective utilization review.

Only one State–North Carolina–had tested the effect of a deterrent charge to the patient. In February 1967, North Carolina required the recipient to pay the first dollar of the cost of each prescription, and at the same time provided beneficiaries with monthly cash payments from which to pay medical expenses. Within about two months,

although the number of prescriptions actually increased, the total cost of the prescription drug program was reduced.

While there seemed to be wide agreement among officials of many States that such a co-payment requirement would probably be a highly effective method of cost control, there was no such agreement on the effect of this technique in limiting the access of welfare beneficiaries to the health care they required.

The influence of limited formularies alone also appears to be questionable. Although the use of a highly restrictive formulary is associated in several States with effective cost control, such control also has been noted in Pennsylvania, with a virtually unlimited formulary but with restrictions on quantity and number of refills.

Many States urged or required the dispensing of low-cost chemical equivalent products where available. Under such conditions, no significant instances of lack of clinical equivalency were reported.

> ***We find, therefore, that in Medicaid and other State public assistance programs, no single method will by itself guarantee program efficiency, but without at least two features–reasonable formulary restrictions and effective data processing procedures–program controls will be ineffective. Although a co-payment requirement may not be widely acceptable in public assistance drug programs, its value in controlling costs in other programs seems evident.***

### *Private Programs*

Several nongovernmental programs to provide prescription drugs to members of unions and other groups have been in operation in this country for many decades, and others have been developed in more recent years.

For special examination, the Task Force selected six of these–Prepaid Prescription Plans, Inc.; Paid Prescriptions, Inc.; United Mine Workers; the Kaiser Foundation Health Plan; Group Health Cooperative of Puget Sound; and the new Blue Cross plan.

As in the case of State programs, these private programs offered a variety of approaches. Some utilized their own pharmacies. Several used restrictive formularies, while others reimbursed for any prescribed product.

All were financed through monthly dues or premiums.

Major economies in these private plans were found associated with the use of formularies, frequent field audits to determine actual acquisition costs by vendors, and the use of a co-payment or similar requirement. The greatest economies were noted in those programs in which the institution served as the purchaser of the drug products, rather than as a reimburser, and thus could obtain competitive or negotiated bids.

Several of the programs included in this study either urged or required the use of available low-cost chemical equivalents. No significant problems with lack of clinical equivalency were reported.

### *Foreign Programs*

The greatest experience with prescription drug programs has been achieved in a number of foreign countries. Fifteen of them in eleven nations were selected by the Task Force for special study–Australia, Belgium, Denmark, France, Great Britain, The Netherlands, New Zealand, Norway, Sweden, West Germany, and the provincial programs of Alberta, British Columbia, Manitoba, Ontario, and Saskatchewan in Canada. Less intensive studies were conducted on the programs in Italy and Switzerland.

All of these nations show wide variations in demographic characteristics, government operations, industrial development, social philosophy, local tradition, and even medical tradition, and certain portions of their health insurance programs may not be suitable for use in the United States. Nevertheless, most of the procedures considered for prescription drug insurance programs in this country have already been tried in one form or another in these foreign programs.

In all of the countries included in the Task Force study–which represent nearly all of the major prescription drug programs in the world–the program is financed by employee or employer contributions, or by voluntary or compulsory participation in various ''sickness funds'' and insurance plans.

Some, including several of the Canadian programs, are designed exclusively for public assistance beneficiaries. Others cover the entire population, regardless of economic status, while still others have programs providing one set of benefits to welfare beneficiaries or pensioners, and another set to those who are not public assistance recipients.

Most of the prescription drug programs, especially in Europe, are integral parts of national health insurance systems.

In most countries for which statistical data are available, it is

evident that there has been a steady increase in the average number of prescriptions per year, in the average prescription cost, and in the cost of the entire program. The prices of specific drug products and of average prescriptions are generally lower than those in the United States; these differences appear to reflect lower labor costs, lower purchasing power, and similar factors, and also more intense price competition among drug manufacturers.

In nearly all countries surveyed in this study, a formulary of one type or another is used to improve rational prescribing, ensure drug quality, and control costs. In most, but not all cases, there are provisions for prescribing an unlisted drug when this is clinically indicated.

The drug lists of Norway, Sweden and Denmark are structured to provide only essential drugs for serious diseases. In France, Great Britain and West Germany, formularies are essentially unlimited, and in the last two countries are noncompulsory; all three of these countries, however, are currently considering the use of more restrictive formularies.

In Australia and New Zealand, and in several European countries, formularies have proved to be highly effective in controlling costs. The Australian government, for example, has no authority to set prices for drugs but uses inclusion in the formulary as an indirect means of price control–that is, if the price is considered too high in relation to its therapeutic advantages by a committee of medical advisors, a drug may not be included in the list. New Zealand negotiates prices, but will pay only at the level established for an acceptable chemical equivalent where one is available. Most of the countries have either established maximum retail prices or negotiated price agreements with manufacturers.

Compulsory licensing of patents is provided by law in most of the countries, but the law is seldom invoked. It may be used if the manufacturer of an ''essential'' or ''necessary'' drug refuses to reduce its price to what the health program considers to be a reasonable level.

With the exception of France, all countries in this group reimburse the drug vendor rather than the patient. The price paid to the vendor is usually determined on the basis of acquisition cost plus an established percentage markup, a dispensing fee, a container fee, or a combination of any of these. In The Netherlands, a capitation system is used in which the patient is required to have his prescription filled at a single

pharmacy, and the pharmacist is paid a per capita fee for each patient registered with him.

In several countries, drug utilization review is provided through central or local boards or committees of physicians. In New Zealand, for example, medical representatives visit physicians to discuss drugs, local prescribing patterns and any individual prescribing habits which might seem to represent irrational prescribing. In Australia and Great Britain, these visits occur when the individual physician's prescribing pattern appears to represent unusually high costs.

Nearly all of these countries recommend or require the use of low-cost chemical equivalents where available. No significant problems with lack of clinical equivalency have been reported. Controversy over generic-name prescribing in Australia, New Zealand and most of the European countries studied by the Task Force has not reached the heights noted in the United States.

Quality control in many of the countries is achieved by registration of all drugs sold in the country, as well as by various types of drug testing. Often a drug evaluation committee or commission composed of physicians, pharmacists, and drug industry representatives has the responsibility for determining which drugs will be registered and which tests will be imposed. Testing varies from batch analysis to complete laboratory research of the formulation and its possible side effects.

Some programs call for patient participation through a fixed co-payment or percentage co-insurance. The effect of such a requirement was demonstrated in Great Britain, when the co-payment requirement was abolished and program costs promptly rose substantially.

* * *

From a survey of the major governmental and private prescription drug programs in the United States and foreign countries, the Task Force finds that–

> ***Establishment of an out-of-hospital prescription drug program for the elderly or for other population groups has been shown to be economically feasible in many countries.***
>
> ***Rational prescribing, with due regard to quality of health care as well as to program costs, can be improved through the cooperation of physicians, pharmacists, drug manufacturers, and a governmental agency.***

***Reasonable program costs appear to be associated with (a) the use of a formulary developed by or in cooperation with the medical community, (b) the use of co-payment or co-insurance, (c) the use of utilization review procedures to prevent or minimize irrational prescribing, (d) the use of appropriate electronic or other data processing methods, with appropriate drug coding techniques, (e) simplified determination of beneficiary eligibility, (f) population coverage which obviates the adverse selection of high-risk beneficiaries, (g) the use of a vendor payment formula based on actual acquisition cost verified by field audits rather than any catalog or wholesale list price, and (h) operation with the program serving as the legal purchasing agency, with utilization of competitive and negotiated bids, rather than merely as the reimbursing agency.***

* * *

***From its consideration of ongoing prescription drug programs, the Task Force finds that a permanent mechanism is needed at the Federal level to collect, analyze and exchange information, and to provide effective coordination of drug-related activities among the agencies involved.***

***We therefore recommend that the Federal Interdepartmental Health Policy Council should concern itself with the coordination of all ongoing Federal prescription drug purchase and reimbursement programs.***

***We recommend that a special subcommittee of the Council should be appointed for this purpose.***

## *CHAPTER 6*
## *DRUG QUALITY*

Intimately related to the costs of drugs in any insurance program is the quality of those products. Involved here is not only the financial soundness of the program; more significant is the quality of health care which is being provided.

During the past eighteen months, the Task Force has considered

various aspects of drug quality, and reported on a number of significant developments:

- Programs undertaken to evaluate the adequacy of existing drug standards and to institute changes in those standards necessary to assure the clinical equivalency of chemically equivalent drugs.
- Steps taken by the Food and Drug Administration to strengthen the enforcement of its regulations concerning Good Manufacturing Practices.
- The review of the efficacy of some 2,900 drugs first marketed between 1938 and 1962 which have been under examination by the National Academy of Sciences/National Research Council.
- The successful drug quality control program of two of the Government's major drug-purchasing agencies, the Department of Defense and the Public Health Service, as well as those of several foreign nations.
- A special study instituted by the Task Force for the objective determination of the biological equivalency of selected chemical equivalents. (This study is described in a following section.)

Despite budgetary restraints and the need to develop new methodology, steady progress has been made in all of these areas.

***Clinical Equivalency***

During the past several years, the clinical equivalency of generic-name products has been the center of particularly heated controversy.

This issue may be presented as follows:

> *Given two drug products containing essentially the same amount of the same active ingredient in the same dosage form–that is, two chemical equivalents–will they produce essentially the same clinical effects?*

This question, of increasing interest to both physicians and patients, is now under careful consideration by the scientific community. Objective research has shown that in certain instances the clinical effects may not be the same.

> ***The Task Force finds, however, that on the basis of available evidence, lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health.***

Where low-cost chemical equivalents have been employed–in foreign drug programs, in leading American hospitals, in State welfare programs, in Veterans Administration and Public Health Service hospitals, and in American military operations–instances of clinical nonequivalency have seldom been reported, and few of these have had significant therapeutic consequences.

Even though such cases are few, and others may well be reported in the future, these cannot be ignored, and the problem deserves careful consideration because of the medical and economic policies which are involved.

The interrelation of medical and economic factors is especially obvious in the case of two chemically equivalent products, both containing the same amount of the active ingredient and both meeting legal standards, but priced at different levels.

If the physician can be given reasonable assurance that two such competitive products will, in fact, give predictably equivalent clinical effects, then his choice between the two may well be based on relative costs. Under such conditions, there would be little justification for prescribing a relatively expensive brand of a drug when an equally effective counterpart is available at substantially lower cost. Similarly, there would be little justification for a Federal drug program to provide for reimbursement of such an expensive brand.

But if the physician cannot be given this assurance, his clinical judgment would dictate that he use only the product which can be expected to yield the desired clinical effects–regardless of cost or any other nonmedical factor.

The physician should be given assurance–not in the form of advertising, promotion, or the established image of the manufacturer involved, but in the form of objective, scientific data. In view of the thousands of drug products on the market, the accumulation of such data might seem to be monumental. But, with the exception of a few drugs for which adequate analytical methods are currently unknown, the Task Force has noted that the problem is by no means insoluble.

### *Clinical Equivalency and Biological Equivalency*

For the direct determination of *clinical equivalency*, it would be necessary to compare drug products containing the same active ingredient, in the same tablet or capsule or other dosage form, in the

same amounts, and measurement of their relative effects in human patients in the alleviation of symptoms or the control of a specific disease.

Except perhaps in rare instances, such a comparison appears to be impractical at this time. It would be time consuming and costly. It would be complicated not only by individual human differences but by differences in the symptoms or diseases under consideration.

Clinical equivalency studies could be conducted in experimental animals, but the nature of specific diseases and the nature of drug absorption and action in animals and human beings may not be directly comparable in all cases.

Instead, attention has been directed to the use of *biological equivalency*–or relative biological or physiological availability–measured in normal subjects as a proxy for the direct measurement and comparison of therapeutic effects.

This is based on the general agreement among pharmacologists that with most drugs–certainly those taken orally for their effect on internal tissues and organs–their therapeutic effectiveness will be closely related to the absorption of the active ingredient into the blood stream.

Thus, it is assumed that if the active ingredient in two or more chemically equivalent products reaches the blood (or other fluid or tissue)–and becomes biologically or physiologically available–at the same time and in the same amounts, their therapeutic effects will be essentially the same.

Among the formulation factors which may be involved here, and involved in any possible nonequivalency of orally-ingested products, are particle size; crystal form; the pressures and other conditions used in tabletmaking; and adjuvants, such as substances incorporated as fillers, lubricants, binders, coatings, flavorings, colorings, and tablet-disintegrating agents.

Attention has also been directed toward physicochemical tests which might be used to indicate biological equivalency. Perhaps the most important of these is the dissolution rate. Once a drug is dissolved in the gastrointestinal fluid, absorption is usually rapid. It is not surprising, therefore, that reported instances of clinical nonequivalency are rare among drugs which are highly soluble or administered in solution but most frequent among drugs of inherently low solubility which are administered in solid dosage forms such as tablets and capsules.

***Biological Equivalency Trials***

In consideration of the foregoing, the Task Force initiated a program in the fall of 1967 to determine scientifically the biological equivalency of a number of chemical equivalents.

A major phase of the investigation was an attempt to determine whether any observed differences in biological equivalency could be related to differences in the physical or chemical characteristics of the products.

It was recognized at the outset that such trials were urgently needed for relatively few drugs. For example, among the 409 products most widely used by the elderly–and which accounted for about 88 percent of all prescription drugs dispensed to this group, there were only 86 which were dispensed under brand name but could have been dispensed under generic name from one or more additional suppliers. An additional 30 were actually dispensed under generic name.

Among these, the priority for clinical trials was determined on the basis of the following criteria:

- The product is generally considered as a ‘‘critical’’ drug–that is, required for the control of a disease, rather than for the alleviation of temporary symptoms.
- It is generally dispensed in solid form–as a tablet or capsule.
- The active ingredient is relatively insoluble.
- Particular attention should be given to those drugs which had previously been the subject of reported or suspected nonequivalency or therapeutic failure.

A number of drugs meeting these criteria–together with a few others chosen for special study–were selected by the Task Force in consultation with representatives of clinical medicine, pharmacology, pharmacy, brand-name and generic-name manufacturers, the Food and Drug Administration, and other governmental agencies. Among these drugs, listed in alphabetical order, were the following:

| | |
|---|---|
| Aminophylline | Para-amino-salicylate, sodium |
| Bishydroxycoumarin | Potassium penicillin G |
| Chloramphenicol | Potassium penicillin V |
| Chlortetracycline | Prednisone |

Diethylstilbestrol
Diphenhydramine
Diphenylhydantoin
Erythromycin
Ferrous sulfate
Griseofulvin
Hydrocortisone
Isoniazid
Meperidine
Meprobamate
Oxytetracycline
Quinidine
Reserpine
Secobarbital sodium
Sulfisoxazole
Tetracycline
Thyroid
Tripelennamine
Warfarin sodium

(It must be emphasized that inclusion in this list does not necessarily indicate that any or all generic-name products are or are not biologically equivalent.)

Biological equivalency studies on these products in human volunteers began late in 1967 in the FDA laboratories; at Georgetown University, under an FDA contract; and at the Public Health Service Hospital in San Francisco.

(Detailed results of these investigations are not presented in this report. Since they will obviously be of practical concern to physicians and scientists, the data are being announced–as quickly as they become available–in the usual medical and technical publications. It is expected that products will be removed from the market as an essential step in improving the quality of health care where legally and clinically significant nonequivalence has been established.)

As an important part of these trials, attempts are being made to determine whether any observed differences in biological availability could be correlated with differences in any physico-chemical characteristics of the product. Such physico-chemical differences could presumably be utilized in developing new and improved specifications for drug quality testing.

***The Task Force recommends that the present clinical trials to determine the biological equivalency of important chemical***

***equivalents should be continued by the Department of Health, Education, and Welfare on a high priority basis.***

In earlier interim reports, the Task Force indicated that these biological equivalency trials would be reasonably up-to-date by 1970.

***As a more realistic projection, we find that the drug quality studies undertaken by the Food and Drug Administration are expected to be adequately if not completely up-to-date by 1971, and thus will provide reasonable assurance of uniform drug quality by that time.***

***Drug Cost and Clinical Equivalency***

Various proposals have been presented under which the Secretary of Health, Education, and Welfare, in Medicare and other drug programs, would be empowered to provide reimbursement at a higher price if the manufacturer could substantiate a claim that his product possessed ''distinct therapeutic advantages'' over a chemical equivalent product. These suggestions have been carefully considered by the Task Force.

Although this double-standard approach appears to present certain economic advantages, it also presents obvious clinical hazards.

In the case of chemical equivalents available from two or more sources, we are convinced that the primary objective should be to provide the physician with every reasonable assurance that all chemical equivalents of the same drug on the market–when administered in the same manner and in the same dose–will give essentially equivalent clinical results. Unless the drugs perform reliably in the clinical situation, the physician will find himself in an intolerable situation, with the possibility that he may be placing the health or even the life of his patient in jeopardy.

Accordingly, when the patent on a product expires and it becomes possible to market chemical equivalents, the original drug product–by virtue of the clinical experience accumulated through its use, and because physicians will have become familiar with its characteristics–should serve as the *reference product*.

As recommended by the Food and Drug Administration, any generic-name counterpart thereafter proposed for introduction should be required either (a) to match the reference product, through conformity with all pertinent USP, NF, or other compendium standards, and, when

required by the Secretary, presentation of appropriate test data to demonstrate essentially equivalent biological availability, or (b) to present acceptable clinical evidence of safety and efficacy through the New Drug Application procedure.

A chemical equivalent which does not meet one or the other of these requirements should not be accepted for Federal reimbursement or purchase, and should not be approved for shipment in interstate commerce.

***We therefore find that there should be uniform standards of quality and efficacy for each drug in any Federally-supported drug program, and that it would be inappropriate to provide for differential cost ranges for products sold under brand or generic names.***

### *Drug Standards*

In the United States, the two most important official compendia of drug standards and specifications are the U.S. Pharmacopeia (USP) and the National Formulary (NF). Both have long and distinguished histories, and are highly regarded by physicians and scientists.

Although both publications have clearly stated that they cannot guarantee it, their standards and specifications have been widely presumed to assure the clinical equivalency of chemical equivalents.

The recent finding that some chemical equivalents are not biologically equivalent, even though they conform to existing USP and NF standards, has shown that certain of these standards may require revision.

During the past year, representatives of both USP and NF have been cooperating closely with the Task Force to meet this challenge. It is expected that existing specifications will be tightened where indicated and possible, and that these modifications will be incorporated in the revised USP and NF editions now in preparation.

The Task Force commends the U.S. Pharmacopeia and the National Formulary for their prompt and responsible approach to the problem of clinical equivalency.

### *Quality Control*

The establishment and enforcement of product standards and specifications represents one important approach to the problem of drug quality and clinical equivalency.

Another is the establishment and rigid enforcement of appropriate

quality control standards in all aspects of drug production and packaging. The Task Force has already recommended that a registration and licensing system be considered under which drug producers and packagers would be required to conform to a code of Good Manufacturing Practices and other criteria.

***We likewise recommend that adequate financial support should be provided to the Food and Drug Administration for necessary educational and inspection operations so that acceptable quality control methods can be instituted and properly maintained in all drug manufacturing and packaging establishments.***

***We recommend that the Food and Drug Administration should be authorized to provide additional support, including grants-in-aid, to State and local agencies in order to improve quality control of prescription drugs in intrastate commerce.***

The enforcement of an acceptable quality control program may be expected to have these effects:

- Many reputable manufacturers, both large and small, already maintain acceptable quality control programs, and will merely be obliged to continue them.
- Some manufacturers may elect not to institute such programs, and their products would therefore be found unacceptable for shipment in interstate commerce.
- Other manufacturers will elect to institute and maintain acceptable quality control methods. This may result in slightly higher production costs, which the manufacturers would most probably cover by setting slightly higher prices on their products.

The Task Force is strongly convinced that the added investment of Federal funds to require acceptable quality control methods, and the slightly higher drug prices that may result in some instances, would be more than justified by the improvement in drug quality that would be achieved.

We have given careful consideration to proposals for the placement of fulltime Food and Drug Administration inspectors in every drug manufacturing plant–large and small–but believe this would involve unjustifiably heavy expenses and inappropriate use of skilled manpower.

We have also considered proposals for the extension of batch certification–now applied mainly for insulin, antibiotics and biologicals–to all drugs, requiring FDA testing and approval at the manufacturer's expense before any batch may be released for distribution. We feel this would place an unnecessarily heavy and costly burden on manufacturers which would be reflected in unnecessarily higher prices to consumers.

Instead, we believe that further study is needed on the use of self-certification, with each manufacturer instituting and maintaining a quality certifying program approved by FDA.

## *CHAPTER 7*
## *GENERIC PRESCRIBING AND DRUG COSTS*

In recent years, as noted elsewhere, the possibility of reducing prescription drug costs by inducing or requiring the prescription of low-cost chemical equivalent products wherever available–an approach known as generic prescribing–has evoked some interest.

Savings can obviously be made by such a method. For example, it has been testified that some patients are required to purchase Meticorten, at $8.50 for 30 tablets, when the drug is available under its generic name of prednisone at $2.58 for the same number of tablets. Similarly, they pay $7.06 for 100 tablets of Serpasil, although it is available under the generic name of reserpine at $2.91. They purchase Achromycin at $5.56 for 16 capsules, even though it is available under its generic name of tetracycline for $3.83.

The substantial savings which could be made by generic prescribing in such specific cases are apparent. The significance of such differences when measured against a total drug program, however, has not heretofore been examined. Establishment of the Master Drug List in this Task Force study has afforded an opportunity to examine the situation in more detail.

Among the 409 products in the MDL were 86 which were dispensed under brand name, but which were no longer protected by patent and could have been purchased under a generic name from one or more additional suppliers. In the case of 23 of these multiple-source products, however, the chemical equivalents were available at only the same or higher cost, and offered no opportunities for savings.

There remain, therefore, 63 products which could have been obtained from multiple suppliers at a cost distinctly lower than that of the brand-name product actually dispensed.

For these 63 products, the use of low-cost chemical equivalents could have reduced the total acquisition cost to the retailer from nearly $74.9 million to $33.4 million, representing a potential saving of $41.5 million, or 55.3 percent at the wholesale level.

The saving to consumers would depend in part on the markup established by the pharmacist:

- If the markup were set so the pharmacist would receive the same gross profit as before ($1.81 per prescription)–neither gaining nor losing by dispensing a low-cost chemical equivalent–the total retail price would be reduced from $150.0 million to $108.5 million. This would represent a saving to consumers of the full $41.5 million, or 27.7 percent on the 63 drug products involved.
- If the markup were set at $1.50 per prescription, the saving would be $54.4 million, or 36.3 percent.
- If it were set at $2.00 per prescription, the saving would be $33.8 million, or 22.5 percent.

The impact of such potential savings on the entire drug program would be less significant. Thus, when measured against the total retail cost of $612.3 million for all 409 drugs on the Master Drug List, a saving of $41.5 million would have these effects:

- A saving of 8.0 percent with a $1.50 markup by the pharmacist.
- A saving of 6.1 percent with a $1.81 markup (which was the actual markup received by the pharmacist on these prescriptions).
- A saving of 5.0 percent with a $2.00 markup.

It must be emphasized that these calculations are based simply on cost levels for these drug products as they existed in 1966. They are not concerned with any differences which might have existed in the quality of the respective products, nor with any administrative or other costs which would be involved in any drug program requiring generic prescribing, nor with any use of formularies or other guidelines.

Savings might be more substantial in later years, since patent protection would expire on some drugs listed as single-source products on the 1966 Master Drug List, and low-cost generic could

appear as competitive items. On the other hand, it appears reasonable to expect that new patented drugs would be added year after year to the list of most frequently used products, and the overall change would therefore not be appreciable.

Although the savings indicated above as a percentage of a total program–about 5 to 8 percent–may not seem large, any economy of the order of $41.5 million per year can scarcely be considered insignificant. Moreover, such savings would involve many products used in long-term maintenance therapy, and thus would provide particular help to patients with chronic illness whose drug needs are often the most burdensome.

For example, among the 63 products for which low-cost generic-name counterparts were available, sizeable savings could be achieved notably with drugs prescribed for long-term use in the treatment of heart disease, high blood pressure, kidney disease, arthritis and related conditions, and mental and nervous conditions.

***The Task Force finds, therefore, that the use of low-cost chemical equivalents can yield important savings, especially in the case of patients with cardiovascular disease, kidney disease, arthritis, and mental and nervous conditions, and the use of such products should be encouraged wherever this is consistent with high-quality health care.***

## *CHAPTER 8*
## *FORMULARIES*

Another point of major controversy in recent years has been the use of a formulary in any proposed drug program. One of the obvious characteristics of this dispute is the lack of agreement on what kind of formulary the disputants are proposing or opposing. Thus, a formulary is apparently considered to be any one of the following:

- A list of *standard* drugs (as established by an officially designed body).
- A list of *recommended* drugs (as established by an individual, a group of experts, a medical society, a government agency, a hospital, an insurance plan, or a group of advertisers).
- A list of *approved* drugs (as established by a government agency, a hospital, or an insurance plan).

In this report, the word formulary is used to indicate a list of approved drugs or drug products–a drug listing restricted in order to achieve more rational prescribing, or economy, or both.

With the aid of expert consultants, the Task Force has reviewed a wide variety of such formularies, giving primary attention to those used by hospitals, and by American and foreign drug programs.

### *Foreign Drug Programs*

A survey of national drug programs in a number of foreign countries has shown that formulary use ranges from restricted formularies, including only a few hundred items, to comprehensive formularies containing almost every drug on the market.

Some specify the drugs for which reimbursement will be provided. Others list the diseases for which drug therapy is covered.

Where formularies are employed, they are used to improve the quality of treatment as well as to control costs. They include only drugs which are believed to be safe and effective. In the case of the more restrictive formularies, those products which are considered by the medical community to be duplicative–offering no significant therapeutic advantages over other products on the market–are not listed. Where low-cost chemical equivalents are available, they are usually included rather than their more expensive brand-name counterparts.

There are usually provisions for reimbursement for an unlisted drug if the physician indicates that it is essential for the appropriate treatment of a specific patient.

In order to control rising drug expenses, there are moves in those countries which do not use formularies to require them in the future, and in those countries with large formularies to make these more restrictive.

Even in those countries with relatively restrictive formularies, but with the selection of drugs made by expert committees of clinicians and scientists, the utilization of formularies appears to be associated with general acceptance by practicing physicians and pharmacists, more intensive competition among manufacturers, relatively effective price control, and few, if any, reported problems related to therapeutic equivalency.

It is noteworthy that many major American drug manufacturers are able to compete successfully under such conditions, and have their products accepted for formulary inclusion.

### *Federal Programs*

Under current programs, formularies are used in all military, Veterans Administration, and Public Health Service hospitals and clinics, but generally not in the drug vendor programs of these agencies. Each Neighborhood Health Center operating under the Office of Economic Opportunity may determine for itself whether it will use a formulary. As noted below, inhospital care under Medicare requires the use of an official compendium or a hospital formulary.

### *State Programs*

Of the States with Medicaid or other welfare drug programs, thirteen are currently using a formulary system. These vary in the number of items from approximately 100 in Kentucky to almost 2,400 in Pennsylvania. Some States list specific drugs, while others list the diseases for which drug therapy is covered.

Most State formularies show classes or types of drugs that are not reimbursable, such as over-the-counter items, nonnarcotic analgesics, multivitamins, anti-obesity drugs, sustained release medications, and tranquilizers. Many place limits on maximum quantities, the number of permitted refills, or the maximum price for any prescription.

Some States encourage generic prescribing by basing reimbursement costs on the price of generic-name drugs.

There are usually provisions which permit reimbursement for an unlisted drug required for unusual situations.

In most instances, the State formulary was developed on the basis of recommendations by expert committees of physicians and pharmacists, although one State has used a formulary which is essentially a list of the most widely advertised brand name drugs.

Opinions on the advantages and disadvantages of such State formularies are divided. In some States, the use of a formulary is believed to be responsible for controlling costs, while in others a proposed formulary was rejected as impractical. In some, the use of a formulary has apparently been found generally acceptable by physicians, while in others it was opposed as implying that the State condoned second-rate medicine for welfare patients. Some State officials have held that a formulary, by restricting the choice of drugs, violated the rights of both physicians and patients.

Some physicians have voiced strenuous opposition to the use of a

State formulary developed by an expert committee, even while agreeing to practice in a hospital in which a similar formulary was developed by a similar group of experts.

The concept of formularies for State programs has not received any significant support from major drug manufacturers.

Although exact comparisons are impossible, it appears that average prescription prices in welfare programs are roughly 10 percent lower in those States using formularies. Although program costs can be limited by reducing the number of reimbursable items in a formulary, this is not necessarily so; for example, an overly-restrictive formulary may serve as an incentive to abuses which will raise total costs to very high levels. Similarly, even under an almost unlimited formulary, costs can be effectively controlled by limitations on maximum quantities dispensed and the number of permitted refills.

### *Private Insurance Programs*

As in the case of State welfare programs, there is no agreement on the need for formularies in drug programs operated by unions, group practice organizations, insurance companies, and other private groups.

Where formularies have been applied–and applied most effectively–in such operations, their use has usually been associated with drug procurement on the basis of competitive bids.

### *Hospitals*

Many American hospitals–including most of the major university and medical center hospitals–have developed formularies for their own use, partly as an educational guide to their staff physicians, and partly to cope with the inventory problems of their pharmacies.

The importance of such formularies was heightened by the Social Security Amendments of 1965, which stipulated that reimbursement for drugs used in the treatment of hospitalized patients in the Medicare program would be approved only if such drugs were included in the U.S. Pharmacopeia, the National Formulary, or similar standard compendia, or if they were in a formulary adopted in an accredited hospital by action of its pharmacy and therapeutics committee.

Enactment of the Federal Medicare legislation was followed in December 1965 by a resolution of the Joint Commission on Accreditation of Hospitals of the American Hospital Association and the American Society of Hospital Pharmacists to add pharmacy and therapeutics committee practices to the functions of an accredited hospital.

The American Hospital Association, the American Society of Hospital Pharmacists, the American Medical Association, and the American Pharmaceutical Association have joined in recommending a hospital formulary system for all hospital staffs ''in the interest of better patient care.''

Most hospital formularies include from several hundred to more than a thousand items. One major New York hospital has reported that a formulary of less than 500 drug products will cover all but 1 percent of the drugs needed for both inpatient and outpatient care.

Provisions are usually included for furnishing unlisted products required for unusual conditions.

Many hospital formularies encourage or require the prescribing and dispensing of chemical equivalents wherever these are available.

In developing these formularies, most pharmacy and therapeutics committees have generally found it unnecessary to include the overwhelming majority of combination of duplicative drugs on the market. In the case of hospitals, formularies make possible substantial economic savings since each hospital usually purchases its drugs on bids, producing keen competition between manufacturers on the basis of quality and price.

> ***In general, the Task Force finds, American physicians have found a formulary acceptable and practical, especially when it is designed by their clinical and scientific colleagues serving on expert committees, when quality is considered at least as important as price, when the formulary can be revised at appropriate intervals, and when there are provisions for prescribing unlisted drug products where special clinical conditions so demand.***
>
> ***We find that the use of a formulary is not a mark of second-class medicine, but is, in fact, associated with the provision of the highest quality of medicine in the outstanding hospitals in the Nation.***
>
> ***Although use of a formulary is not a guarantee of high quality medical care, rational prescribing, effective utilization review, and control of costs, we find that the achievement of these objectives in a drug program is difficult if not impossible with it.***

In the interests of achieving the highest quality of medical care, we recognize the necessity of placing the fewest possible restrictions on

the traditional right of physicians to prescribe according to their best clinical judgment.

Therefore, it seems appropriate that consideration should be given to the reimbursement or purchase of unlisted drugs or drug products under emergency conditions or when a physician demonstrates to an appropriate formulary committee or local pharmacy and therapeutics committee that this is essential for the well-being of a specific patient.

## *CHAPTER 9*
## *QUALITY AND COST STANDARDS*

Since implementation of the Medicare and Medicaid programs, increasing public attention has been focused on the cost of prescription drugs, particularly where Federal and State expenditures are involved, and on the possibility of utilizing suitable quality and cost standards to improve these programs.

Among the factors that are obviously involved are these:

1. *Drug Prices*. Many brand-name products are available under their generic names at substantially lower prices (see Chapter 7). The Department of Health, Education, and Welfare encourages the dispensing of such low-cost chemical equivalents where they are available and where their use is consistent with high quality health care. Federally-aided State programs, however, are under no obligation to follow this policy.
2. *Retail Markup*. Many pharmacists use a percentage markup of drug acquisition cost as a basis for establishing the retail price of a prescribed product. Others have adopted a fixed dispensing fee system which allows the same dollar return to the vendor, regardless of product cost. The relative advantages and disadvantages of these systems are now a matter of some dispute (see Chapter 3).
3. *Formularies*. A number of State programs limit reimbursement to specific drugs listed in a formulary. There is little consistency among these formularies, however, and many include drugs which are felt by the formulary committees of other States to be unnecessary for rational therapy (see Chapter 8).

4. *Clinical Equivalency.* Considerable controversy has occurred in recent years concerning the comparative efficacy of brand-name drugs and lower-cost chemical equivalents. Recent evidence of biological nonequivalency among a few drugs has created doubts among physicians and their patients about the efficacy of low-cost chemical equivalents in general (see Chapter 6).
5. *Government Expenditures*. The funds involved in these governmental programs are substantial. For example, the Federal and State governments spent about $208 million for prescription drugs for welfare recipients alone in fiscal year 1968. As implementation of State Title XIX programs continues, drug expenditures for the medically indigent will increase.

***Legislative Action***

The Task Force has carefully examined these and other factors in considering whether the Federal Government can and should impose more effective controls upon costs of drugs supplied in the programs specified by the House and Senate legislation.

One Task Force study, for example, was undertaken in response to Section 405 of the Social Security Amendments of 1967 which states that:

> ''(a) the Secretary of Health, Education, and Welfare is authorized and directed to study . . . quality and cost standards for drugs for which payments are made under the Social Security Act . . . ''

After consideration of the question of whether the Federal Government can exercise more effective controls on the costs of drugs supplied in the Medicare, Medicaid, and Maternal and Child Health programs, we presented a preliminary report as follows:

''1. The drug quality control studies [undertaken by the Food and Drug Administration] are expected to be adequately if not completely up-to-date by 1970, and this will provide reasonable assurance of uniform drug quality by that time.
''2. Establishment of reasonable cost and charge ranges for drugs provided under the Medicare, Medicaid, and Maternal and Child Health programs is feasible, and would reduce the cost of drugs to the Federal and State governments without sacrifice of quality.''

On the basis of these preliminary findings, the Task Force recommended legislation to permit establishment of reasonable cost and charge ranges–the limits of Federal participation in reimbursement–for drugs supplied to patients in the three programs noted above. Thereafter, the Department endorsed legislation introduced in both the House (H.R. 16616) and the Senate (S. 3323) to establish such cost and charge ranges.

H.R. 16616 and S. 3323 were identical except for the wording of a proposed Section 1122 (a)(1)(A) in S. 3323. Each bill would have required the Secretary to establish guidelines showing a ''reasonable cost range'' for drugs dispensed to patients under health programs supported with Federal funds. The Secretary would be required to exclude from the reasonable range those prices which varied significantly from the price of the drug when sold by its established–or generic–name. He would be empowered to recognize a differential price for a brand-name drug, however, if the manufacturer could substantiate a claim that his product possessed ''distinct therapeutic advantages'' over a generic-name product.

Defined in each of the bills was a ''reasonable charge'' for drugs. This charge would be the lesser of (1) the cost of the drug within the ''reasonable cost range'' plus a reasonable fee or billing allowance, or (2) the pharmacist's ''usual or customary charge.''

In addition, the Senate version would have required the Secretary, in effect, to establish a formulary of drugs appropriate for use in the Federal and State programs–a feature that was currently under study by the Task Force and which, for that reason, was not endorsed by the Secretary.

In its study of these legislative proposals, the Task Force has been concerned with three major questions:

- Can the Federal Government provide adequate assurance that low-cost chemical equivalents will be of sufficiently high quality and provide essentially the same clinical effects as drugs sold by their brand names and often at higher cost?
- Is it feasible to limit Federal expenditures for drugs to those specified by the Secretary, with the expert advice of the medical community?
- Would the limitation of Federal expenditures for drugs to cost and charge ranges at which products are available by their generic names result in significant cost savings?

To all three questions, the Task Force has noted, the answer is yes.

***Assurance of Clinical Equivalency***

As noted above, we have found that the drug quality studies undertaken by the Food and Drug Administration are expected to be adequately if not completely up-to-date by 1971, and these–together with modification of existing drug standards, strengthened enforcement of the FDA's Good Manufacturing Practices regulations, and other steps–will provide reasonable assurance of uniform drug quality by that time.

***Scope of Drug Benefits: Impact of a Formulary***

The Task Force has examined the use of limited drug lists or formularies in hospitals and in a wide range of government and private drug programs in this country and abroad. In general, such formularies have been found to be useful guides to rational prescribing, and provide an effective means of cost control when developed by or in close cooperation with physicians who represent a broad spectrum of clinical and academic experience.

As a guide to predicting cost savings in Federally-supported drug programs, the experience of existing State formulary systems presents some difficulties. Each formulary may cover a different range of drugs, and many have restrictions on prescription quantities. Some limit the maximum price of an individual prescription or the total annual reimbursable expenses per beneficiary. Others restrict the use of particular drugs to certain disease conditions, some encourage or require the prescribing or dispensing of low-cost chemical equivalents, while still others are structured to favor brand-name drugs. Certain formularies omit ''non-critical'' drug classes, such as anti-obesity agents, nonnarcotic analgesics, antacids, or tranquilizers, and some include an ''escape clause'' which allows the dispensing of nonlisted drugs under certain conditions.

Although all of these factors may affect the costs of a drug benefit program to different degrees, it seems evident that the use of a restricted formulary can lower the costs of a drug program. This observation is borne out in reports on hospital formulary experience, a comparison of State welfare programs, and from the experience of social insurance programs in other countries.

***From a survey of the available evidence, the Task Force finds that the exclusion of certain combination products, duplicative***

***drugs, and noncritical products from Federal reimbursement would contribute significantly to rational prescribing, and moreover, it seems reasonable to assume this could yield overall savings of at least 10 percent.***

### *"Reasonable Cost" Ranges*

If reasonable assurance of uniform drug quality is a logical prospect by 1971, the relative costs of chemically equivalent drugs will become a significant economic factor in drug benefit programs.

To analyze the potential cost savings which could be achieved by the dispensing of generic-name products, the Task Force initiated a study of the 409 drugs most frequently dispensed to the elderly. It found that 63 could have been obtained from a number of suppliers at a cost distinctly lower than the brand-name products actually dispensed. Maximum savings at the retail level would have ranged from 23 to 36 percent on these 63 drugs, or between 5 and 8 percent when applied to all 409 drugs.

***From studies conducted by the Task Force and others, we find that establishing product cost ranges reflecting the cost of drugs generally available by their generic names would save approximately 5 percent at the retail level.***

### *"Reasonable Charge" Ranges*

Pharmacists usually apply the same pricing system to both drug and nondrug products by using a percentage markup, or margin, system. The markup for most items stocked in pharmacies averages about 50 percent of cost; for prescription drugs, it ranges from 65 to 100 percent or more of acquisition cost.

The American Pharmaceutical Association and other professional groups have advocated in recent years a flat dispensing fee to reflect actual professional costs. This approach is widely used among hospital pharmacies and some government and private drug insurance programs, and it is being adopted by a number of community pharmacies. Among the advantages cited for the fixed fee system are these:

- It removes an incentive to stock and dispense high-cost drug products when low-cost chemical equivalents are available.

- It makes clear that the dispensing function bears little relation to product cost and therefore emphasizes the professional service rendered by the pharmacist.
- By reducing the cost of high-price medications and increasing the cost of low-priced items, it eliminates the subsidization of some patients by others.

By itself, the employment of a dispensing fee reimbursement system does little to assure that reimbursement for pharmacy services will equitably achieve the desired economies. Rather, techniques should be developed so that the allowance will be designed to reflect only those expenses which are directly related to the dispensing function. No portion of program payments should be made for unrelated functions or for vendor services that are grossly inefficient.

***Although the Task Force is convinced that significant program savings could be achieved through the application of techniques designed to improve the efficiency of vendor operations, it is impossible at this time to estimate the extent of these savings.***

### *Administrative Procedures and Costs*

The establishment of reasonable cost and charge ranges for drugs, as envisaged in S. 3323 and H.R. 16616, would entail new methodology and significant administrative costs. In addition to the drug quality and equivalency activities already under way, mechanisms would be needed at both the Federal and State levels to assume other new responsibilities involved in the proposed legislation. Among these would be the following:

1. Establishment of an expert advisory committee of physicians, pharmacologists, and pharmacists to advise the Secretary on the qualification of specific drugs and drug groups for cost reimbursement.
2. Improvement of Federal resources for the determination of drug acquisition costs, development of audit and compliance procedures, drug utilization review methods, and techniques to increase the efficiency of drug distribution.
3. Mechanisms to provide technical assistance to the States in developing and improving their drug benefit programs.

Although considerable experience has been gained at the Federal level–in part the result of Task Force activities–that would permit the swift and efficient discharge of some new responsibilities, others would take many months from the date of enactment.

***We find that considerable time would be required to develop all the necessary administrative mechanisms. Therefore full implementation of such provisions as applied to Federal reimbursement for prescribed drugs cannot be assured in less than two years after enactment of appropriate legislation.***

In a preliminary report to the Chairman of the Senate Finance Committee on an earlier similar proposal, S. 2299, former Secretary of Health, Education, and Welfare, John W. Gardner, submitted Task Force staff estimates of administrative costs which were in excess of $100 million during the first year and approximately $34 million annually after the first five years.

The bulk of this projected expenditure would have been for improved quality control and for drug product testing to be conducted by or for the Formulary Committee envisaged in S. 2299.

Secretary Gardner recognized, however, that the improvement of drug quality would benefit not only those eligible for drug benefits in Federally-assisted programs but all users of prescription drugs.

Indeed, since the staff report in 1967, the improvement of drug quality and the studies of clinical equivalency have become matters of high priority within the agencies charged with these responsibilities and these priorities are reflected in substantial budget increases.

***Any necessary increases in Federal expenditures for the improvement of drug standards and quality control will have benefits which apply to all users of prescription drugs and should not be attached to the implementation of cost standards for drugs supplied in Federally-assisted programs.***

Significant costs would be incurred, however, solely from the enactment of the proposed legislation. If the provisions of S. 3323 were to take effect in fiscal year 1972, we estimate that the net incremental costs to the Department of Health, Education, and Welfare and the State programs would be as follows:

| | FY 1972 (millions) | Subsequent years (millions) |
|---|---|---|
| Determination of "appropriate" drugs | $ 1.3 | $ 0.7 |
| Determination of product costs | 1.4 | 0.6 |
| Determination of dispensing allowances | 0.9 | 0.5 |
| Publication of drug lists, guides, and other informational materials | 1.2 | 1.2 |
| Technical assistance to State agencies and compliance review (Titles V and XIX) | 1.6 | 0.6 |
| Incremental costs of State agency audit (Titles V and XIX) | 0.4 | 0.4 |
| Review of drug providers (for exemption from provisions of the act–Title XVIII) | 0.5 | 0.3 |
| Costs of administration to non-exempt providers (Title XVIII) | 0.4 | 0.3 |
| Total administrative costs | $ 7.7 | $ 4.6 |

## *Projected Savings*

At the present time, Medicaid programs are in effect in 43 States and other jurisdictions. Of these, 36 provide reimbursement for the costs of prescription drugs. Drug expenditures under the program totaled $239.5 million in fiscal year 1968, approximately 7.8 percent of all Medicaid expenditures. In addition, $3 million was spent for drugs under the various Maternal and Child Health programs. It is anticipated that joint expenditures for drugs under these programs may rise to approximately $300 million by mid-1971.

If drug expenditures do, in fact, reach $300 million in that year, and if the projected savings outlined earlier in this report are applied, the following program savings could be expected:

| | | Savings (Millions) |
|---|---|---|
| Potential savings | | |
| Establishment of "reasonable cost ranges" | $ 15.0 | |
| Specification of cost-reimbursable drugs | 30.0 | $ 45.0 |
| Less administrative expenses (first year) | | 7.7 |
| *Net Savings (first year)* | | *$37.3* |

These figures could vary substantially, however, with such factors as the development of an out-of-hospital drug benefit program under Title XVIII, the costs to drug producers of developing and supplying data needed to substantiate drug quality, the extent to which the States develop their own mechanisms for limiting drug expenditures, and the effectiveness with which Federal quality and cost standards are applied at the State level.

***From a consideration of the projected costs and savings, we reaffirm our earlier finding that establishment of reasonable cost and charge ranges for drugs provided under the Medicare, Medicaid, and Maternal and Child Health programs is feasible, and would reduce the cost of drugs to the Federal and State governments without sacrifice of quality.***

## *CHAPTER 10*
## *DRUG CLASSIFICATION AND CODING*

***Within a few years, it may be expected that prescription drug benefits under existing public and private programs will involve several hundred million prescriptions annually.***

***Without a universal coding, classification and identification system–a common language for communicating essential information–the Task Force finds that the administrative and accounting costs for processing such a volume will inflate program costs beyond acceptable limits.***

To find methods of coping with this problem, the Task Force appointed *ad hoc* committees of experts on classification and coding which began a series of meetings in July 1967. In these conferences, criteria were established for a system under which all known pharmaceutical preparations could be identified and desired data stored and retrieved by use of existing and planned electronic data processing techniques and equipment.

### *Classification*

The proposed classification system is now in final draft. It is the result of the joint efforts of representatives of the American Medical Association, the U.S. Pharmacopeia, the National Formulary, the

American Society of Hospital Pharmacists, the Drug Information Association, the National Pharmaceutical Council, the Pharmaceutical Manufacturers Association, the Food and Drug Administration, the National Library of Medicine, and various universities and State agencies.

Based on the vital necessity to relate cost analysis and utilization studies to how and why drugs are being used, the classification scheme is designed to accommodate products by categories reflecting their intended therapeutic action. This version makes it possible to place drugs in multiple settings. Final data collection will survey these settings and provide cost breakdowns and other cost analyses according to actual drug usage.

Application of the classification will have obvious importance for economic administrative procedures. More significantly, it will play an important part in developing information needed for improving the quality of health care.

> ***The Task Force recommends that the Department of Health, Education, and Welfare, the Department of Defense, and the Veterans Administration should test the proposed drug classification system to determine the feasibility of its eventual use in all public and private drug programs.***

We commend those whose efforts made possible the development of the system.

### *Coding*

In the different aspects of drug manufacturing, distribution, sales, use, utilization review, accounting, cost analysis, and other marketing or administrative procedures, many different kinds of information may be needed. Basic to all of them, however, is information which will identify (a) the manufacturer, (b) the product, dosage form and strength, and (c) the package size, and which also is in a form which can be transmitted, stored and retrieved through electronic data processing systems.

Logically, the identification number would be assigned for all drugs on the market, and for any new drug at the time the New Drug Application is approved.

The number should be part of the required labeling, and ideally could be used to identify each individual tablet or capsule by printing techniques which are already being used by some drug manufacturers.

In addition, the number should be utilized in the coding for a proposed international adverse drug reaction reporting system which is now under consideration.

As a result of Task Force studies, it appears that an appropriate code can be developed by the use of a nine-character identification system utilizing both letters and numbers. The first three numbers would identify the labeler of the product (in most cases the labeler would also be the manufacturer), the next four would identify the drug, dosage form and strength, and the last two would identify the package size.

It is believed that such an identifying system would be able to accommodate a virtually unlimited number of different drug products.

The Task Force recommends that–

***a. an appropriate identifying code number should be made part of all drug labels, package inserts, catalogs and advertising.***
***b. An appropriate coding system should be developed and tested by government and industry for this purpose.***
***c. After consideration of the results of this test, appropriate legislation should be introduced to require coding of all drug products in interstate commerce.***

We commend those whose efforts are making the development of a new coding system possible.

As part of its activities in the field, the Task Force also supported development of an experimental National Drug Code Directory, prepared in preliminary form by the Food and Drug Administration to serve as a directory of essentially all prescription and over-the-counter drugs.

***We recommend that the drug code adopted by government and industry be utilized in the National Drug Code Directory.***

## *CHAPTER 11*
## *UTILIZATION REVIEW*

In any drug program, utilization review is a dynamic process aimed first at rational prescribing and the consequent improvement of the quality of health care, and second at minimizing needless expenditures.

In many hospitals, staff committees of experts have long taken the responsibility of reviewing the records of their fellow physicians and offering such advice or taking such disciplinary action as they deemed necessary. During the past two years, utilization review programs have been instituted to improve the quality of medical care under the hospital program of Medicare. Similar reviews are used in several American and foreign drug programs to improve the quality of drug prescribing.

It should be the responsibility of a program administration to institute a drug utilization review, and provide the necessary data and whatever statistical analysis may be required.

But the implementation–the establishment and improvement of guidelines, the provision for acceptable deviations, the limitation of irrational prescribing, the prevention of fraudulent practices, and other professional judgments–should be mainly the responsibility of clinicians, pharmacologists, and pharmacists who are widely respected as objective, well-informed, and appreciative of the needs of both physicians and patients, and who would work with their colleagues at the State and local level.

***We find there is an urgent need for further research to develop and test various approaches to effective utilization review–approaches which would be most acceptable to physicians, pharmacists, consumers and others, and which would obtain their effective support.***

***We therefore recommend that the National Center for Health Services Research and Development, in cooperation with State and local medical groups, community pharmacies, hospitals, and consumer groups, should support pilot research projects on prescription drug utilization review methods.***

## *CHAPTER 12*
## *DRUGS UNDER MEDICARE: THE ISSUE OF COMPREHENSIVE COVERAGE*

Since July 1, 1966, the Medicare program–Title XVIII of the Social Security Law–has provided coverage for almost all of the inpatient hospital expenses of the elderly and for a significant proportion of

their expenses for physicians' and other medical services. As a result, out-of-hospital prescription drug expenses represent the largest single personal health expenditure that the elderly must meet almost entirely from their own resources.

In 1967, for example, prescription drugs accounted for about 20 percent of the personal private health expenditures of older people.

It is not surprising, therefore, that there has been much interest on the part of the Congress in covering out-of-hospital prescription drugs under Medicare. Since 1965, more than 50 bills have been introduced to cover drugs under this program. In 1966, a bill that would have covered prescription drugs under the Supplementary Medical Insurance Program (Part B of the Medicare program) was passed by the Senate, but the drug coverage provision was deleted in conference.

Similar interest on the part of the Executive Branch of the Federal Government was marked by the presidential directive that led to establishment of the Task Force on Prescription Drugs to study the problems involved in covering the cost of prescription drugs under Medicare. At the request of the Task Force, the Social Security Administration–the agency that would have primary responsibility for administering a drug benefit under Medicare–has taken main responsibility for studying the feasibility of alternative methods of covering out-of-hospital prescription drugs.

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The primary reason for proposing that an out-of-hospital drug benefit be provided for the elderly under Medicare, rather than through some other means, is based on the fact that the Medicare program has proven to be a highly successful method of financing the high health costs incurred by the elderly. The program has gained widespread acceptance among the elderly themselves, the health care community, and those who contribute to the program. Coverage of out-of-hospital prescription drugs under Medicare would relieve the elderly of part of the economic burden associated with their high drug costs, and would also represent an important step in assuring that their total health care needs are adequately met. The Task Force believes that, to the extent that it is possible to do so without incurring unreasonably high administrative costs, an out-of-hospital drug program under Medicare should be designed in such a way that

beneficiaries will be able to understand it easily, and will not be unduly burdened by the procedures for obtaining benefits.

The specific provisions of an out-of-hospital drug benefit under Medicare would have to be developed within the context of the administrative complexities involved in a drug benefit and the funds available for financing the new benefit. One of the most important considerations affecting these factors is the scope of the drug benefit to be provided.

Most of the legislative proposals for coverage of drugs under Medicare that have been introduced in the Congress thus far would have covered drugs on a comprehensive basis–that is, they would have covered the majority of the approximately 1200 different legend drugs on the market.

There is no doubt that such comprehensive coverage of drugs under Medicare would represent a considerable financial benefit for the elderly. Comprehensive coverage, it should be noted, does not imply coverage of all prescription drugs. Even the most nearly complete drug coverage provided in existing programs have limits on the drugs covered and establish limiting conditions under which payment for drugs would be made; for example, it is the common practice of many private insurance and other drug programs to exclude from coverage certain classes of drugs–e.g., anti-obesity drugs, multiple vitamins, nonnarcotic sedatives, antacids, etc.–whose medical necessity is often marginal. However, even after such drugs are excluded from coverage, the numerous and complex administrative problems and very high program costs that would be involved in covering the remaining drugs present strong arguments for not attempting to provide comprehensive coverage in the first stages of a new drug program under Medicare.

### *Administrative Problems*

One very important consideration in developing a plan for the coverage of drug expenses of elderly people is that there would be an extremely large volume of bills for covered services if comprehensive coverage were provided.

- It is estimated that the elderly would obtain more than 300 million prescriptions in the first year of operation.
- These prescriptions would be obtained through some 54,000 community pharmacies and some 3,000 hospital outpatient departments, as well as other providers of drugs to outpatients (e.g., mail-order firms, extended care facilities, clinics, and dispensing physicians).

The magnitude of the administrative tasks implied by these figures can be appreciated by comparing them to operating statistics for the first year of Medicare:

- During fiscal year 1967, some 10.4 million claims were processed by the hospital insurance intermediaries, while 26.5 million claims were processed under the medical insurance part of the program–a total of less than 37 million claims.
- The covered services were provided by about 7,000 participating hospitals, 4,000 extended care facilities, 2,000 home health agencies, 2,000 independent laboratories, and more than 170,000 physicians.

Even though the pharmacists and other drug vendors submitted combined or composite bills for covered drugs, the volume of items to be processed under a comprehensive program would obviously be much greater than that under the present Medicare program. While the claims transactions with respect to prescription drugs would be fairly simple, and there would be no variation in the types of data required for each claim, preliminary administrative planning indicates that each prescription involved in a claim for drug benefits would entail a minimum of half a dozen items of information, all of them subject to being transcribed incorrectly, either by machine or by hand.

Under these conditions, it is clear that efficient administration of a drug program of such a magnitude requires a fully automated data processing system operating with a high degree of accuracy.

During the beginning stages of any major new program, the use of automated data processing systems frequently involves problems arising from faulty operation of newly installed equipment, improper programming and human error. Furthermore, in any automated process, some items need to be handled manually because they contain discrepancies. If anything approaching the percentage of items for manual handling usually considered acceptable were excepted from the automated drug claims process, there is a possibility that the claims process would suffer a serious breakdown.

While these problems generally diminish over time and as experience is gained, it seems quite essential at the beginning to limit the number of claims items to be processed to a size which would keep within acceptable limits the risks involved in establishing a new system of processing. And even under a limited drug coverage

program, it would be desirable to provide for a considerable period of time to prepare for administration of the benefit.

An additional consideration is that a large proportion of prescriptions are relatively inexpensive. Under these circumstances, it is difficult but important to develop provisions for administration so that costs associated with claims processing would not be excessively high in proportion to the benefits received by the beneficiary.

A final consideration is that in terms of the scope of benefits that would be involved, there is only limited useful precedent in either private insurance or governmental drug programs from which to develop the administrative procedures needed if a comprehensive drug benefit of this magnitude were provided.

### *Cost of Comprehensive Coverage*

Another important consideration relating to coverage of most of the prescription drug expenses of the elderly under Medicare is the high cost associated with such coverage. The Social Security Administration had indicated that the ''high-cost'' estimate for comprehensive coverage of prescription drugs under Medicare, assuming a 20 percent co-insurance and an effective date of 1971, would be $1.6 billion, exclusive of administrative costs. (This estimate assumes a per capita acquisition of 21.5 prescriptions, and an average price per acquisition of $4.58.)

### *The Case for Less-Than-Comprehensive Coverage*

There are, then, sound reasons why, in the first stages of administering a drug program, the Medicare program should not attempt to meet virtually all of the drug expenses of all older people. In fact, there is some question whether it would ever be desirable to attempt to provide insurance protection against small annual drug expenditures. A more effective use of program funds might result if an effective system could be found for limiting the benefits in a way that would concentrate the protection where it is most clearly needed.

Adoption of a limited approach would be consistent with the purpose and philosophy underlying Medicare–and, in fact, the entire social security program. The program is designed to encourage beneficiaries to build additional protection through private insurance, individual savings, and private pension plans. And, while cash benefits are intended to provide meaningful wage replacement for

fulltime regular workers, it has always been recognized that some individuals will have special needs that cannot be met through the combination of private initiative and the social insurance mechanism, and that there will be a continuing but declining need for assistance programs.

Similarly, the Medicare program, by providing protection against only those expenses which the elderly as a group have the greatest difficulty in meeting, assumes that individuals will continue to meet part of their own health expenses, that private health insurance will be of continuing importance in meeting the health care expenses of the elderly, and that medical assistance programs will play a continuing, though supplementary, role.

***The Task Force finds that, because of the numerous and complex administrative problems and the high program costs involved in providing drug coverage under Medicare, it would be desirable–at least at the outset–to provide the benefit on a less-than-comprehensive basis.***

## *CHAPTER 13*
## *DRUGS UNDER MEDICARE: COVERAGE UNDER PART A OR PART B*

Under present law, the Medicare program consists of two separate parts, the hospital insurance program (Part A) and the supplementary medical insurance program (Part B).

- Under the hospital insurance program, which is financed through payroll contributions, virtually all of the elderly are entitled to benefits.
- In contrast, enrollment in the supplementary medical insurance program is voluntary, and medical insurance benefits are provided on a current-premium basis.

All of the proposals thus far introduced in the Congress to cover out-of-hospital drugs under Medicare would have provided this coverage under Part B of the Medicare program, and the Congress requested that the Secretary of Health, Education, and Welfare study the possibility of coverage under Part B; because of certain problems evident in covering prescription drugs under Part B, however, consideration has also been given to coverage under Part A.

In terms of the coverage of out-of-hospital drugs under Medicare, there are two fundamental aspects–eligibility for benefits and financing–in which coverage under Part B would have significantly different results from those under Part A.

While there are other important differences between the two parts of the Medicare program–especially in the areas of claims processing and reimbursement–these do not represent fundamental differences between the two programs, and could be modified if a drug benefit were added. For example, while under Part B at present the beneficiary generally initiates a claim for benefits, if a drug benefit were added to Part B it would be entirely feasible to rely on drug vendors to initiate the claim for drug benefits. (These nonbasic differences between Part A and Part B are discussed where appropriate in Chapters 15 and 16, which discuss issues relating to administration and reimbursement.)

### *Eligibility for Benefits*

Participation in Part B depends at least in large part on an individual's ability to pay the monthly premiums, which are matched by contributions from Federal general revenues. As of July 1, 1968, 18.6 million people aged 65 or over–95 percent of the elderly–were enrolled under Part B of the Medicare program.

It is clear that most of the elderly feel they need the protection that Part B offers, and it is expected a high proportion of them will continue to participate in this voluntary part of the program. Nonetheless, while some of the elderly who have not enrolled under Part B either feel they do not need or do not want the protection offered by the program, it is likely that many who have not enrolled simply cannot afford the monthly premium. There is, of course, no way to predict what effect future increases in the Part B premium will have on enrollment under that plan.

If, on the other hand, out-of-hospital drugs were covered under Part A of Medicare, virtually all people now aged 65 or more would be automatically eligible for the new benefit. As of July 1, 1968, 19.7 million persons aged 65 or more–99 percent of the elderly–were eligible for hospital insurance under Medicare, including some 2 million individuals who were not insured for social security or railroad retirement cash benefits but who were eligible for hospital insurance under a special ''transitional'' provision, which is financed out of

general revenues. (For men who attain age 65 after 1974–for women 1973–the special eligibility requirements provided under the transitional provision will merge with the regular requirements for social security benefits.) Individuals who are not eligible for benefits under the transitional provision include retired or active Federal employees and their spouses who are eligible for health insurance coverage under the Federal Employees Health Benefits Act of 1959 and who are not eligible for monthly cash benefits under social security or the railroad retirement program, and certain aliens who have been in this country for only a short time. It is expected that when the social security program is fully mature, from 95 to 98 percent of all the elderly will be eligible for hospital insurance benefits; ineligible persons will be only those who are not entitled to monthly cash benefits under social security or the railroad retirement program.

Another important consideration is that Part B eligibility lapses if the beneficiary elects to withdraw from the plan or if he fails to pay the monthly premium, while eligibility under Part A continues until a person's death. The experience of Title XIX drug programs indicates that the process of determining eligibility for benefits under a program in which continuing eligibility cannot be assumed constitutes one of the most expensive and troublesome parts of the claims process.

***Financing the Drug Program***

If a drug benefit were provided under Part B of Medicare, the program would be financed through the monthly premiums paid by beneficiaries, and the matching government contribution paid out of general revenues. This method of financing the drug benefit has several drawbacks.

For one thing, the additional premium needed to finance the benefit might prove sufficiently burdensome for the elderly who have to pay the present monthly premium so that more of them might decide to reject coverage under Part B. If a provision similar to Amendment No. 440 were enacted, providing for a drug benefit under Part B–which represents the approach introduced most frequently in the Congress–the cost of the benefit would be $4.60 per capita per month. (Under this approach, the beneficiary would be responsible for a $25 drug deductible in addition to the $50 Part B deductible under the present law, and payment would be made for 100 percent of the ''allowable expenses'' with respect to a given drug.) The monthly

premium rate and the matching amount paid out of general revenues would each have to be increased by $2.30 to finance the new benefit. Amendment No. 440, of course, would have provided comprehensive coverage of drug expenses, and a more limited approach under Part B would be less costly.

It should be remembered, though, that in 1966, 53 percent of the Nation's aged individuals, and 11 percent of the families in which the head was aged 65 or over, had an income of less than $120 a month, while 29 percent of aged individuals, and 30 percent of families in which the head was aged 65 or over, had an income of between $120 and $240 a month.

Thus, many would find an increase in their monthly premium (currently $4)–even if it were less than $2.30 with a less-than-comprehensive coverage–to be a significant amount to pay from their low incomes. In addition, the insured person would also be responsible for the $50 annual deductible and a 20-percent co-insurance for covered medical services other than drugs, plus a $25 deductible applicable to covered drug expenses, and any amounts in excess of the ''allowable drug expense'' as well as any incurred health costs not covered under the Medicare program.

An additional consideration is that under Part B, increases in health costs or substantial increases in utilization of covered services must be paid for, through increases in the beneficiary's monthly premium, on a year-to-year basis as the cost increases occur.

In contrast, if a drug benefit were provided under Part A, the program would be financed through the regular contributory mechanism now used to finance hospital costs and the cash-benefit part of social security. Under this approach, an individual would pay for this protection during his working years, rather than at a time of life when he may well have low income, limited assets, and high health costs. In addition, increases in the health costs and the utilization of services covered under Part A can be assumed in establishing the contribution rates and thus averaged and paid for over a substantial period of time. Also, with contributions based on earnings, increases in the general earnings levels that can be expected to occur in the future will automatically provide additional income to the system to help meet increases in health costs.

***The Task Force finds that while it would be feasible to provide coverage of out-of-hospital prescription drugs under either the***

***hospital insurance (Part A) or medical insurance (Part B) programs of Medicare, there would be significant advantages, in terms of beneficiary eligibility and financing, in providing such coverage under the hospital insurance program.***

## *CHAPTER 14*
## *DRUGS UNDER MEDICARE: ALTERNATIVE PROPOSALS FOR COVERAGE*

Three possible methods of covering out-of-hospital prescription drugs under Medicare would appear to be of most value to beneficiaries with high drug costs, and would result in more limited program costs and a lower volume of claims than would occur under essentially full coverage. These alternatives are:

- Coverage of only those drugs important for the treatment of serious chronic illnesses which afflict the elderly.
- Coverage of most prescription drugs, combined with the use of a relatively large annual deductible applicable to drug expenses.
- Coverage of most prescription drugs, but with eligibility for the drug benefit restricted to social security beneficiaries who have attained age 70 or, alternatively, age 72.

These proposals embody, respectively, three common techniques for limiting the scope of a drug program: limiting the number of covered drugs; relying on a high cost-sharing factor; and limiting the number of eligible beneficiaries.

There are other techniques which would contribute to limiting program costs and which could be incorporated into any of the three proposals. Among them are these:

- Setting maximum limits on the cost of prescriptions to be reimbursed.
- Setting maximum limits on the quantity of a drug per single prescription for which reimbursement would be made.
- Discouraging over-utilization through the use of such cost-sharing mechanisms as co-payment or co-insurance applied to each prescription, and through utilization review.

These techniques are discussed in Chapter 16.

Coverage along the lines of any of the proposals discussed here could be provided under either Part A or Part B of the Medicare program.

### *Coverage of Long-Term Maintenance Drugs*

Available data on drug use by the elderly support the hypothesis that coverage of only those drugs which are important for the treatment of chronic illness among the elderly, and which usually are required on a continuing or recurring basis, would concentrate the protection provided by a drug program where it is most clearly needed.

(As indicated in Chapter 1, there is wide variation among the elderly in the extent to which they use prescription drugs: those older people who have serious chronic illnesses use more drugs than those who are not chronically ill, and many of the drugs most frequently used by the elderly are associated with the serious chronic illnesses which afflict older people.)

Under such an approach, the Medicare law could provide that the Secretary of Health, Education, and Welfare would establish the list of specific drugs to be covered under the program. He would select those drugs which he finds are important in the treatment of the many serious chronic conditions which afflict the aged. Once a drug was so specified as a covered drug, reimbursement would be made without regard to the condition for which it was prescribed. The law might also include guidelines indicating how the list would be established. Also, to assist the Secretary in establishing the list of covered drugs, the law might provide for an Advisory Council on Drugs, including nongovernmental experts in pharmacology, pharmacy, geriatrics and other branches of clinical medicine, and representatives of consumer groups.

The statutory guidelines on the selection of drugs to be covered would authorize the Secretary to consider whether, both absolutely and in relation to other drugs in its therapeutic class, a drug was (1) of acceptable quality; (2) safe and efficacious, giving careful consideration to relative toxicity and taking into account studies by the Department of Health, Education, and Welfare, the Department of Defense, the Veterans Administration, and other agencies which the Secretary found to be appropriate; and (3) not unduly expensive in relation to its therapeutic efficacy.

The drugs selected could include, in addition to drugs which can only be dispensed upon prescription by physicians, certain drugs which can be dispensed without a prescription (e.g., insulin) but only if the Secretary found that such drugs were ''lifesaving drugs,'' or that their withdrawal would be seriously harmful to individuals who had been using them, or that they provided acceptable substitutes in terms of economy and effectiveness for other drugs included in the list.

The guidelines would require that the list be reviewed and revised as necessary, at least once each year, and that the Secretary be required to report to the Congress annually on the adequacy of the list and the cost of the drug benefits being paid.

If such an approach were adopted, it is estimated that the level cost of the new benefit, if provided under Part A of the Medicare program and assuming a $1 co-payment, would be 0.19 percent of taxable payroll (estimated on a ''high-cost'' basis and exclusive of administrative costs). On the assumption that 1971 would be the first year of operations, benefit payments in that year would amount to an estimated $720 million, with reimbursement made for about 135 million prescriptions.

A more limited approach might be the restriction of coverage to drugs which are important in the treatment of a limited number of specific, serious chronic conditions; for example, the list of covered drugs might be limited to those which are important in the treatment of cardiovascular disease, diabetes, kidney conditions and respiratory conditions. Such an approach would involve somewhat lower workloads and benefit costs than would be concerned in coverage of drugs important in the treatment of virtually all the chronic conditions of the elderly.

Coverage of such a limited number of drugs appears to be the most promising of the alternative methods of providing limited drug coverage that the Task Force has considered. This approach would have the administrative advantages of limiting the number of claims submitted for processing, and of providing the most protection to those of the elderly who, because they have recurring needs for drugs associated with chronic illness, can be assumed to have the greatest need for such benefits.

While such an approach might entail some problems of beneficiary understanding related to what drugs are covered, these problems do not appear to be insurmountable.

One indication of the feasibility of covering only a limited number of specific drugs for the treatment of chronic illness is that Norway and Denmark have adopted such a method of covering drugs under their social insurance health care systems.

In this country, a similar approach has been used successfully by the drug program of the United Mine Workers Welfare and Retirement Fund; in 1967 this program provided drugs for 500,000 eligible beneficiaries. (The closed panel United Mine Workers program is organized on a regional basis, with each region establishing its own formulary; the number of drugs in these formularies ranges from 64 to 148. Prescriptions are covered under the program only if they are obtained from physicians who have entered into participating agreements with the plan.)

Every effort would be made to help assure beneficiary understanding and to provide physicians and pharmacists with easily understandable information about the drug benefit, including an easy-to-use listing of all drugs covered under the program.

A more fundamental possible drawback to this approach is that there is a question whether widespread medical agreement can be reached on the drugs to be selected. Although it would, of course, be impracticable to compile a final list of ''covered'' drugs far in advance of the effective date of drug coverage, continuing work should be done to develop lists of drugs in the therapeutic categories associated with treatment of chronic illness.

One question that needs to be explored in depth is whether a medically acceptable list of important drugs used in the treatment of chronic illness would include a disproportionately large number of drugs that are often used in the treatment of *both* chronic and acute illnesses, and whether a significant portion of benefits might therefore go for prescriptions to treat acute, short-term illness.

As indicated earlier, data from the Master Drug List (which reflects some 88 percent of the prescriptions obtained from community pharmacies by the elderly in 1966) indicate that a relatively small number of drugs account for a high proportion of the prescription drugs used by these individuals. Although the Master Drug List provides merely an index of recent prescribing patterns, and does not necessarily reflect expert medical judgments as to what is good drug therapy or what drugs are most significant for treatment of serious illness, it serves at least as a guide to the number of frequently

dispensed legend drugs in the various therapeutic categories associated with the continuing or recurrent treatment of the important chronic illness of the aged. The Master Drug List data indicate that there are fewer than 200 such drugs which are relatively frequently used for such purposes.

> ***In order to achieve maximum benefits with whatever funds may be available, and to give maximum help to those of the elderly whose drug needs are the most burdensome, the Task Force finds that particular consideration should be given to providing coverage at the outset mainly for those prescription drugs which are most likely to be essential in the treatment of serious long-term illness.***

***Use of a High Annual Deductible***

A second possible method of limiting the number of claims and program costs of a drug program under Medicare would be to pay benefits only where a beneficiary's drug expenses exceed a specified, relatively high annual amount.

Serious consideration has been given to a proposal under which virtually all legend drugs would be covered, subject to a $100 annual deductible, with a co-insurance of 20 percent to be paid by the beneficiary on drug expenses above that amount. Beneficiaries would be responsible for keeping records and submitting claims for reimbursement, and would be permitted to submit claims only after accumulating charges which equal the deductible amount.

Under this approach, the pharmacist would be asked to certify that a drug was available only on prescription and was provided for the use of the named beneficiary. The pharmacist's certification would appear on each receipt for a covered drug.

The beneficiary would collect and submit his receipts for covered drugs in a pre-addressed envelope furnished by the Social Security Administration. Reimbursement would be made directly to the beneficiary, on an indemnity or ''reasonable charge'' basis.

In comparison with comprehensive coverage, this proposal would result in substantial reductions in both program costs and claims levels. It is estimated that the cost of the proposal would be $405 million in the first year of operation, and that reimbursement would be made for about 100 million claims in that year. If the benefit were provided under Part A, it is estimated that the level-cost of the

proposal would be 0.14 percent of taxable payroll (based on the ''high-cost'' estimate and exclusive of administrative costs).

Of the three methods of limiting the administrative burden of a drug benefit considered by the Task Force, this proposal could be designed in a way that would permit the highest degree of administrative simplicity. Not only would claims levels be greatly reduced, but a large part of the recordkeeping burden would rest with the beneficiary, rather than with the Social Security Administration. Moreover, the Administration would not, under some approaches, have to enter into agreements with the 54,000 community pharmacies or with the approximately 3,000 other dispensers of drugs. The process of negotiating such agreements and of maintaining ongoing relationships with participating drug vendors would obviously result in a substantial workload. An additional consideration is that drug vendors would not be required to keep records for reimbursement purposes.

Also, although this approach to coverage is patterned after the claims and reimbursement provisions in effect under Part B, there is no necessary relationship between the indemnity approach followed under Part B and the Part B financing mechanism. It would be possible, therefore, to follow the indemnity approach referred to above even if the eligibility and financing provisions of the new benefit were established under the hospital insurance part of the program.

The main drawback to an approach involving a $100 deductible is that, for a beneficiary with heavy drug expenses and limited resources, $100 is a very large amount of money, and a deductible of this size would mean that drug expenses would remain a real hardship to many beneficiaries. While a lower deductible amount could be established, this would result in increased workloads and program costs.

For example, a $75 annual deductible with a 20 percent co-insurance, provided under Part A, would involve benefit costs of about $535 million in the first year of operation, with reimbursement being made for an estimated 140 million prescriptions, and an estimated level-cost, exclusive of administrative expenses, of 0.18 percent of taxable payroll.

If the deductible were $50, assuming no other changes in the provisions just listed, benefit costs would be $710 million, reimbursement would be made for an estimated 190 million claims, and the level-cost would be 0.25 percent of taxable payroll.

Another drawback to a high deductible approach is the difficulty

that beneficiaries would have in keeping track of their drug expenses. Under this approach, assuming an average cost of $4 per prescription, the beneficiary might have to accumulate as many as 26 prescriptions before he could be reimbursed for any of his drug expenses. Experience with the $50 annual deductible under Part B indicates that Medicare beneficiaries have great difficulty keeping track of their medical bills, especially those for small amounts, and supports the inference that the higher the deductible amount, the more serious the problems.

Furthermore, to a great extent the administrative and cost advantages of such an approach are based on the assumption that the administering agency would be engaging in only a minimum amount of claims administration. For example, since validity of a claim would rest primarily on a pharmacist's certification that the receipt was for payment of a prescription drug dispensed to given beneficiary, there would be opportunity for abuse of the benefit–such as beneficiaries procuring drugs for other members of their families or for their neighbors. The additional expenses involved in preventing such abuse would detract from the administrative and cost advantages of the proposal.

***From a consideration of these factors, the Task Force finds that the use of an annual deductible to control costs presents opportunities that warrant further consideration.***

***Pay Benefits at Age 70 or 72***

A third approach to providing a limited drug benefit under Medicare which would reduce the cost and the number of claims involved would be to make the benefit available only to those who attain a certain age–for example, age 70 or age 72.

Under this approach, payment might be made for the great majority of the 1200 different legend drugs on the market, offering the benefits of a comprehensive program although to only a limited portion of the elderly. Only 65 percent of the present population aged 65 and over are 70 and over, and would therefore be eligible for benefits (53 percent would qualify if the eligibility age were 72).

If the eligibility age were set at 70 and virtually all prescription drugs were covered, the cost of the benefit–assuming a $1 co-payment–would be about $1.2 billion in the first year of operation, and the level cost of the benefit would be 0.42 percent of taxable payroll (estimated on a ''high cost'' basis). If the eligibility age were

set at 72, benefit costs would be about $1 billion, and the level-cost would be 0.36 percent of taxable payroll.

Reimbursement would be made for about 240 million claims if the eligibility age were 70, and 205 million if the age were 72.

Costs and claims levels could, of course, be reduced further by means of cost-sharing provisions.

Apart from the problem of rationalizing age 70 or 72 as the age at which a particular Medicare benefit would become available when all other Medicare benefits are available at age 65, there is a question of whether such a new age limit would be the most effective means of concentrating protection where it is most needed. Medicare beneficiaries under age 70 or 72 who had very high drug costs might well have difficulty understanding a rationale which excluded them from coverage while paying for the drug expenses of people who, while older, were in somewhat better health.

***Restricting benefits to those aged 70, 72 or more would reduce the size and cost of the program, but the Task Force finds that this is not a preferred approach at this time.***

## *CHAPTER 15*
## *DRUGS UNDER MEDICARE: PROGRAM ADMINISTRATION*

A number of important factors concerned with administrative policies and procedures have been considered by the Task Force. These include determination and demonstration of eligibility, the role of the drug vendors, the role of the administrative agency, certification by physicians, the question of utilization review, and the need for a delayed effective date.

### *Establishing Beneficiary Entitlement*

If a drug benefit were included under Part A, a beneficiary's entitlement to the out-of-hospital maintenance drug benefit would be established at the same time as entitlement to hospital insurance benefits. In virtually all cases, such entitlement could be expected to continue until the beneficiary's death, and this fact would greatly simplify administration of the benefit. Once entitlement were established, the beneficiary identification procedures now used for the

present hospital insurance program could be applied, and the pharmacist could assume that a beneficiary who presented an identification card indicating Part A entitlement was, in fact, entitled to Part A drug benefits. If the benefit were provided under Part B, such a presumption would be in error if the beneficiary had failed to pay his premiums or otherwise terminated his enrollment.

It is contemplated that an out-of-hospital drug benefit would be made available only to those beneficiaries who are not hospital inpatients. One consideration in so limiting eligibility is the fact that the great majority of inpatient beneficiaries are in participating hospitals and thus their hospital expenses, including the cost of drugs, are already being paid in large part by Medicare.

No payment for out-of-hospital drugs would be made where an individual was receiving drugs that were already being paid for by Medicare as part of his extended care benefits. For these individuals, out-of-hospital drug benefits would begin when their extended care benefits terminated. At the present time, many persons who receive extended care benefits under Medicare do not have their drug costs met as part of these benefits, since an extended care facility is not required to provide drugs. For these individuals, the out-of-hospital drug benefit would be payable under the new drug program, either to the beneficiary or to the drug vendor, depending on which reimbursement system was adopted.

***Reliance on Drug Vendors***

Administration of an out-of-hospital drug program would be greatly simplified if substantial reliance could be placed on community pharmacies and other vendors for initiating claims.

The major alternative would be a system under which the beneficiary paid for his prescription at the time of purchase, kept a record of his expenses for covered drugs, submitted claims for benefits, and was then reimbursed by the program on the basis of the covered expenses he incurred. With a population of beneficiaries that could be expected to undertake the recordkeeping involved in a considerable number of small claims, this procedure has much to recommend it. Under such conditions, it is probable that many small claims would not be filed, since the beneficiary would decide that it was not worth his while to file claims for very small amounts. The elimination of very small claims would not be altogether inequitable to the beneficiary, and would contribute to efficient administration. As

noted above, reduction of claims volume could be achieved through the use of a sizeable deductible amount with respect to drugs.

This method of claims administration, however, might place an undue burden on many beneficiaries, which could be avoided if the claims process were initiated by the pharmacist rather than the beneficiary.

Administering the drug benefit through payments to drug vendors would have other important advantages in addition to relieving the claims burden that would be placed on the beneficiary if he were responsible for keeping records of his drug expenses. The vendor could submit claims at regular intervals on composite claims forms and receive periodic reimbursement for multiple claims. Recording of claims and collection of program data could be facilitated through such techniques as use of the National Drug Product Code. In addition, if only a limited number of drugs were covered under the program, primary reliance could be placed on the vendor to determine, by reference to the list of covered drugs, whether a particular drug would be a covered drug for which a valid claim could be submitted. Finally, use of automated data processing methods could be more readily employed where claims were submitted by the provider.

Reliance on the drug vendors in the claims and reimbursement process would also facilitate increased coordination of an out-of-hospital drug benefit under Medicare with the drug benefits available under other Government programs–principally Title XIX programs–which make payment directly to the drug vendor. In 1967, Federal vendor payments for out-of-hospital drugs amounted to $100 million and it is likely that all Federal programs involving vendor payments will be even larger in the future.

Reliance on vendors also would enable the Social Security Administration to take advantage of advances in electronic data processing capabilities, including equipment which would permit transmittal of claims information directly from drugstores to the agency processing the claims. At the present time, there are no proven communications systems for use in drugstores that would aid them in meeting the requirements of a drug program under Medicare by tying the drugstore into the automated data processing system. However, from the technological standpoint, there are no significant obstacles to the development of such systems once a program need has been established, and these devices could play an important part in efficient claims administration.

If substantial reliance were to be placed on drug vendors in the processing of drug benefit claims and in reimbursement, it is contemplated that vendors, like the providers of services under the present Medicare law, would be able to participate in the program only if they entered into an agreement to do so with the Secretary of Health, Education, and Welfare.

They would have to agree–

- To accept certain limits on the amounts they would charge program beneficiaries (these limits are discussed in Chapter 16).
- To submit bills with such frequency and in such form as may be specified.
- To make available drug and prescription records for drug audits.
- To keep such checks on the accuracy of the dispensing of prescriptions as may be provided under regulations.
- To meet such other conditions of health and safety as may be provided in regulations.

As drug vendors under the program, it would seem feasible to include community, mail-order and hospital outpatient pharmacies, clinics, and, in certain cases, dispensing physicians. In addition, extended care facilities participating under Medicare would be able to act as drug vendors under the program if they so desired. Where an extended care facility did not want to act as a drug vendor, as discussed above, covered drugs could be obtained from other dispensers of drugs, either by the beneficiary or on his behalf. It should be noted that some minor changes in the definition of the reasonable cost of extended care benefits would be required, to avoid anomalous situations which might arise because of the use of two different methods of making reimbursement for drugs. Some changes in regulations might be needed to assure that the Social Security Administration would not be paying more for a drug purchased from a retail pharmacist but furnished as an extended care benefit than the amount determined to be the ‘‘reasonable drug charge’’ (see Chapter 16) for that same drug furnished under a new drug benefit program.

It would seem desirable that physicians be permitted to act as drug vendors in the program only under certain conditions established by the Secretary. In determining reimbursement of such a dispensing physician, consideration should be given among other factors to the extent of any other professional services he performed at the time he

dispensed the drug, and of any charges he made for those services; that is, the physician should not be reimbursed both for a dispensing charge as part of his ''reasonable charges'' as defined in the present Medicare law for professional services and also for a dispensing allowance in his capacity as a drug vendor.

***The Task Force finds that it would be preferable for the vendor rather than the beneficiary to have major responsibility for keeping needed records and initiating claims, and to be reimbursed by the program.***

### *Role of the Administering Agency*

If a new drug benefit is added to the Medicare program, administrative responsibility should rest with the Secretary of Health, Education, and Welfare, with a primary delegation of authority to the Social Security Administration.

As the legislative specifications develop for the new drug program, and as the many complex problems of designing the most feasible method of administering the new benefit are resolved, it may prove to be desirable to enlist the assistance of nongovernmental organizations. The possible use of other organizations and their specific functions, however, will depend to a large extent on the resolution of other important administrative questions. For example, the nature of the automated data processing system that would be used in administering the new benefit would have an important bearing on the delegation of functions to outside organizations.

A highly sophisticated automated data processing system could function most effectively if the drug benefit were administered at the Federal level, but with appropriate consideration of the system's compatibility with systems used by other organizations. An additional consideration here would be the experience and proficiency developed by various organizations in administering drug-benefit claims by the time drug coverage is added to the Medicare program.

***Because of the large number of claims which would be involved, the Task Force finds that a suitable automated data processing system could play a vital role in claims processing and other administrative activities, and should be developed and adequately tested.***

### *Certification by Physician*

The Medicare law excludes from coverage all services and supplies that are not medically necessary. This exclusion should apply to out-of-hospital drugs if they were covered under Medicare.

Under the present law, one of the primary methods of assuring that the Medicare program pays only for services which are medically necessary is the requirement that a physician certify to the need for the services received. In applying such a requirement to an out-of-hospital drug benefit, it is contemplated that the prescription filed with the drug dispenser would be the only certification required for most prescription drugs.

In the case of those drugs which are especially subject to abuse, coverage might be limited to instances in which the drug was prescribed for certain specified conditions. In such cases, the physician would have to provide information beyond the prescription itself.

Some form of certification–such as a physician's prescription–would also be needed with respect to any nonlegend drugs, such as insulin, which were included in the list of covered drugs.

### *Utilization Review*

Utilization review is another technique for helping to limit payments to those for medically necessary services. The concept of utilization review is gaining widespread acceptance in the medical community as an appropriate means of discouraging unnecessary use of medical services and of encouraging improved patient care. By requiring as a condition for participation that hospitals and extended care facilities establish utilization review committees, the Medicare program has been responsible for the establishment of this machinery in most hospitals throughout the country. In the case of drugs, utilization review is being developed primarily to achieve rational prescribing.

It appears, however, that the problems involved in establishing effective utilization review procedures are probably greater for all out-of-hospital services than for services received inside an institution. In the case of drugs, the vast volume of prescriptions, the fact that a given prescription in itself provides information on only a small segment of an individual's total medical history, and the fact that there is not yet complete consensus among physicians on rational prescribing–all these combine to present serious obstacles to the effective implementation of utilization review at the present time.

***The Task Force finds that to the extent that appropriate utilization review methods are developed, these should be applied in a Medicare drug program.***

The Task Force has already noted that there is a pressing need to encourage State and local medical societies and other concerned groups to work toward improving patterns of prescribing and has recommended strong support of research and experimentation with prescription drug utilization review methods.

***Delay in Effective Date***

In preparing this report, it has been assumed that the new drug program would become effective no earlier than two years after the date of legislative enactment. As discussed above, the relative administrative complexity of a drug program would depend on the details of design. Even the simplest form of administration would require a substantial tooling-up period.

## *CHAPTER 16*
## *DRUGS UNDER MEDICARE: PROGRAM REIMBURSEMENT*

The specific provisions relating to reimbursement that are appropriate for a drug program would depend to a large extent on whether the claim is filed by the beneficiary or by the vendor of drugs.

For example, if the ''high deductible'' approach described above were adopted, with the beneficiary submitting his own claims, one feasible method of reimbursement would be the ''reasonable charge'' approach now used under Part B of the Medicare program. Since, however, most of the claims submitted would be for relatively small amounts, many claims would be filed a considerable period of time after the prescription was obtained, and the Social Security Administration would not have entered into any agreements with pharmacists on the records they keep, anything more than a very gross check on the ''reasonableness'' of the charges submitted by the beneficiary would be extremely costly and almost impossible to accomplish.

An alternative method would be to pay claims, once the deductible is met, on the basis of a schedule which would list a flat amount for each item paid for.

If, on the other hand, claims were to be submitted by the pharmacist and reimbursement were to be made directly to him, an entirely different approach to reimbursement would be possible. In evaluating the various possible approaches to such vendor reimbursement, emphasis has been placed on finding reimbursement techniques which would minimize disruptions in the pharmacist's customary methods of doing business–for example, techniques which would minimize the amount of additional recordkeeping and the amount of additional work involved in submitting claims, and which would allow the pharmacist to compute the program payment easily. Beneficiary understanding has also been stressed.

Other important considerations include the need for these factors:

- A reimbursement mechanism that would permit payment to be made on a current basis.
- A mechanism that would permit a reasonable check on the accuracy or appropriateness of payments made by the program without resulting in very high auditing and accounting costs.
- A method which would be acceptable to the drug vendor in terms of the total payment he receives, from both the program and the beneficiary.
- A method which would not reward inefficient operation, would not spend program funds for drugs that are not competitively priced in situations where competitively priced drugs are available, and would give the beneficiary an incentive to be conscious of comparative drug prices.

### *Guidelines in Law*

It would seem desirable that guidelines with respect to reimbursement of providers of drugs would be stated in the law, but that the detailed reimbursement provisions would be established by the Secretary in regulations, after consultation with representatives of all affected groups.

This was substantially the procedure followed in establishing the principles of reimbursement for hospitals and extended care facilities under the present Medicare law.

The provision of a drug benefit under Medicare would, however, involve many more participating drug vendors than there are ''providers of services'' under the present Part A, and these vendors

exhibit a considerable degree of variation in size, function, and volume of pharmacy business, as well as in methods of purchasing, maintaining inventories, and other methods of doing business. It would be important to the success of the program to give representatives of all classes of drug vendors the opportunity to present their views on reimbursement before the Secretary makes final decisions on this matter.

The guidelines in the law would state that reimbursement for out-of-hospital drugs would be made to qualified drug vendors on the basis of the ''reasonable drug charge'' for each drug, and that the ''reasonable drug charge'' would consist of cost elements relating to (a) the acquisition and (b) the dispensing of the drug, to be defined in regulations.

The guidelines in the law would also permit the Secretary, when establishing the reasonable charge, to take into account significant variations in the price at which the drug was made available to different classes of drug vendors with the result that the ''reasonable drug charge'' for a specific drug might vary among different classes of providers in different regions or localities. In addition, the guidelines would require that the regulations concerning the ''reasonable drug charge'' include a provision for periodic review in order to assure the continuing adequacy of the charge.

The Social Security Administration would carry on continuing studies designed to measure changes in the cost of the various elements included in the ''reasonable drug charge.''

***Reimbursement for Product Costs***

Determining the acquisition costs incurred by pharmacists and other drug vendors in furnishing covered drugs to Medicare beneficiaries is the aspect of vendor reimbursement on which probably the greatest amount of additional work is needed. Many different approaches have been utilized in various governmental and private programs in this country and abroad, but none has been demonstrated to be completely adequate. As the Task Force has noted elsewhere, extensive studies are needed on drug costs and drug prices, including further examination of the pricing structure of the drug industry, price changes among different categories of drugs, and related issues.

Among the methods considered by the Task Force as a basis of determining acquisition costs are these:

- Actual acquisition cost, as verified by audit,
- ''Usual and customary'' charges,

- Listed wholesale price,
- Fixed program payment.

Consideration has likewise been given to the significance of acquisition by generic name, government purchase, and establishment of price through government-industry negotiation.

*Actual Acquisition Cost*. Under the present Medicare law, providers of services are generally reimbursed on the basis of the audited actual costs of the covered services they furnish to Medicare beneficiaries. In the case of out-of-hospital prescription drugs, however, basing reimbursement on audited costs would involve substantial administrative expenses, and a significant degree of possible error. The acquisition cost of each covered drug furnished to a beneficiary would have to be determinable and verifiable through audit, yet it would be very difficult to determine with precision the cost incurred by the vendor in actually acquiring it.

Under the pricing system now prevalent in the drug industry, the published wholesale price of a drug product is subject to a complex system of frequently changing discounts, including discounts based on the purchase of other drug products, and cumulative discounts based on volume that may be computed after the end of the accounting year. Thus, in many cases the pharmacist's inventory may have been purchased at several different prices, and it is possible that the costs associated with determining the actual costs of acquiring drugs would be substantial.

*''Usual and Customary'' Charges*. An alternative approach would be to base reimbursement on the pharmacist's ''usual and customary'' charges (including both acquisition and dispensing elements), thereby avoiding altogether any questions to the pharmacist about cost. In many cases, however, payment on the basis of customary charges would result in the program paying amounts for a drug that were far greater than the costs of the pharmacist in actually acquiring it. An additional problem is that a program of anything more than minimal checks on whether a charge was ''usual and customary'' would be exceedingly difficult to administer. Essentially, this approach to reimbursement would place no restraints on the prices that beneficiaries or the program paid for covered out-of-hospital prescription drugs.

While this would seem to be a feasible alternative if the beneficiary, rather than the pharmacist, were to submit the claims for drug benefits, it would seem to be the least desirable approach to vendor

reimbursement, since it would offer no protection against unduly high prices to either the beneficiary or the program.

*Listed Wholesale Price*. Another alternative would be to base reimbursement on the listed wholesale price of a drug product, but, as noted above, these listed prices rarely have any realistic relationship with actual acquisition costs. The assumption here would be that any losses incurred by the program as a result of basing reimbursement on listed wholesale costs would be made up to the program in savings on auditing and other administrative costs.

It would seem desirable, if this approach were adopted, that *Red Book* and *Blue Book* prices not be relied upon as the sole determinants of the wholesale price of a given drug, but that price listings be compiled on a more current and reliable basis.

This approach would have the advantage of administrative simplicity. It would also permit the program to place some limits (discussed below) on the amounts paid by the beneficiary and by the program for a given drug.

*Fixed Program Payment*. Still another alternative would be to establish a fixed program payment with respect to each drug. Under this approach–comparable to indemnity fee schedules in many forms of health insurance–the program payment for a specific quantity of a drug product would be a single uniform amount, and would not depend on either the price paid by the beneficiary or the costs incurred by the pharmacist.

While this fixed payment would not have to bear any relationship to the costs incurred by the pharmacist, it *could* be based on an estimate of probable acquisition costs.

This approach would also have the merits of administrative simplicity and of being easy for the pharmacist to compute and for the beneficiary to understand. Here, too, it would be possible to impose certain limitations (discussed below) on the amounts paid by beneficiaries or by the program.

***The Task Force finds that reimbursement for product cost, as one element in the total cost of a prescription, may be considered on the basis of (a) "usual and customary" charges, (b) listed wholesale price, (c) actual acquisition cost as verified by audit, (d) a fixed program payment. Preference would be determined by the nature of the program.***

***Acquisition by Generic Name***

If the Medicare program and its contributors are to have the benefit of any reduction in costs which results from the availability of a drug from more than one supplier, and from the resultant price competition, it would seem necessary for the element of the ''reasonable drug charge'' related to acquisition costs to reflect the cost of acquiring the drug by its generic name, or, if lower, by its brand name. In most cases, this would be the cost of the drug when acquired by generic name.

It is recognized that under a program covering only a limited number of drugs, a requirement that reimbursement be based on the lowest cost of acquiring a given drug would result in some savings to the program. For example, data in the Master Drug List show that among the 82 drugs in the list that were prescribed for an average of 90 days or more per year, 11 were dispensed by their generic names and an additional 16 were dispensed under brand names but were available under generic name from more than one source. It is estimated that there could have been a 28 percent saving at the wholesale level if these 27 drugs had been purchased by their generic names at the lowest available cost.

If the number of covered drugs were not restricted, the potential saving from basing reimbursement on the cost of a drug acquired by generic name could be even greater. Thus, the Master Drug List shows that of the 409 drugs most frequently dispensed for the elderly in 1966, 30 were actually dispensed under their generic names, and an additional 86 products dispensed under brand names were drugs for which chemical equivalents were available. Together, these 116 drugs accounted for 39 percent of total MDL prescriptions, 37 percent of the MDL acquisition cost to retailers, and 32 percent of the MDL retail cost to patients. It is noteworthy that, in the case of 23 of the 86 drugs for which chemical equivalents were available, the chemical equivalents were available only at the same price as their brand-name counterparts, or at a higher price, and thus offered no opportunities for savings. Nonetheless, for the 63 multiple-source products which could have been obtained at a lower price if acquired by their generic name, the savings could have been considerable: the wholesale cost to the retailer of these products could have been reduced by about 55 percent. It should be noted that this hypothetical saving is based on the assumption that the lowest-priced generic drugs were all of acceptable quality and were available on a nationwide basis.

Although generic prescribing as a required approach presents many attractive features, it has certain evident drawbacks.

For example, any attempt to permit or require a vendor to dispense a low-cost chemical equivalent in place of a drug prescribed under its brand name would necessitate modification or repeal of the so-called ''anti-substitution'' laws now in effect in nearly all States.

There is nothing in these laws to prevent a physician from prescribing by generic name if he so desires. Similarly, there is nothing to prevent a physician from authorizing a pharmacist to fill the prescription with any suitable chemical equivalent. In a number of hospitals and drug programs, special prescription blanks are customarily used to provide such authorization routinely except when the physician specifies otherwise.

One drawback to basing reimbursement on acquisition of a drug by its generic name is that the Medicare beneficiary would have to bear the cost of the difference between the cost of acquisition by generic name and the cost of acquisition by brand name, in those situations in which the physician required dispensing by brand name.

This drawback, while serious, does not seem to be insurmountable. As noted above, even under existing laws, a physician may prescribe generically, or authorize the pharmacist to dispense an appropriate low-cost chemical equivalent. Every effort would be made to acquaint physicians with the names of the drugs covered under the program and with detailed information on how reimbursement would be made for covered drugs, as well as with information on the prices at which a covered drug was generally available.

Before a requirement was adopted basing reimbursement on the lowest acquisition cost, it would be necessary to provide assurance that all drugs on the market are of acceptable quality. In this connection, it should be noted that the drug quality control studies that were undertaken by the Task Force in cooperation with the Food and Drug Administration, the Public Health Service, representatives of the United States Pharmacopeia, the National Formulary and others are expected to be adequately up-to-date by 1971, and should provide reasonable assurance of uniform drug quality by that time. Further assurance could be gained by stipulating in the law that the Secretary could find that an out-of-hospital drug was a covered drug for reimbursement purposes only if it met the Secretary's standards as to quality.

***Accordingly, the Task Force finds that reimbursement for product cost should be based on the cost of the least expensive chemical equivalent of acceptable quality generally available on the market.***

At the same time, it is clear that the Department of Health, Education, and Welfare has the responsibility for keeping physicians, vendors, and the general public informed of the availability, quality and relative costs of chemical equivalents, and for urging physicians to prescribe low-cost chemical equivalents for all beneficiaries of Federal drug programs wherever this is consistent with high quality health care.

***Government Purchase***

Consideration has been given to other techniques which would prevent the Medicare program from paying excessively high prices for drugs, and one noteworthy technique–direct purchase of drugs by the government–was examined particularly by the Task Force.

The case for government purchase of drugs provided under Medicare is based mainly on two considerations: (a) the fact that if drugs were covered under Medicare on a comprehensive basis, the government programs (including Department of Defense, Veterans Administration and Public Health Service programs, as well as programs under the Social Security Act) would be paying, directly or indirectly, for a significant part–an estimated 46 percent–of the total domestic sales of the pharmaceutical industry by 1975; and (b) the assumption that if the government were either to purchase drugs directly, through competitive or negotiated bids, or to purchase patent and license rights and enter into contracts for producing drugs on the basis of the purchased licenses, the cost to the government would be much less than the cost of the same drugs acquired on a retail basis.

In the case of drugs still under patent, statutory authority already exists for the Federal Government to purchase such drugs from non-licensed manufacturers, either in this country or abroad, when this would be justified both by drug quality and by price savings.

In addition, the present drug procurement methods of several government agencies include plant inspection and analyses of quality of the drugs being purchased; if these procedures were adopted on a broad scale, along with purchase of patent or license rights, the government presumably could obtain a given drug at the lowest possible price without sacrificing quality.

There is, of course, widespread concern that prescription drug prices do not reflect price competition in the marketplace, and that as a result the price of prescription drugs is unduly high. The Task Force, however, does not recommend direct purchase of drugs by the government at this time as a means of controlling prices and conserving Medicare program funds. Direct government purchase of drugs for Medicare beneficiaries would have significant disadvantages. The primary purpose of the Medicare program is to provide, through the mechanism of social insurance, a method of financing the major health expenses of older people. Widescale direct purchase of drugs by the Medicare program would require that the program perform functions that are not usually thought of as social insurance, and would also introduce substantial alterations into the drug distribution system in this country.

> ***Since the expressed purpose of the social security program is to provide assistance to beneficiaries, wherever possible, within the framework of the existing health care system, the Task Force finds that the direct purchase of drugs by the Federal Government for Medicare beneficiaries is not recommended at this time, but this approach deserves further study.***

A somewhat related approach would be establishment of acquisition cost on the basis of a price negotiated between the government and manufacturers–a method used in some national health programs. This approach presents some advantages, and warrants further study.

***Reimbursement for Dispensing Costs***

The reimbursement guidelines in the law would state that the elements in the ''reasonable drug charge'' which represent dispensing costs would include such factors as overhead costs associated with dispensing, a fair profit or return, extent of professional services provided, and other relevant factors.

The dispensing cost elements in the ''reasonable drug charge'' might take account of whether the drug product was a legend drug or an ''over-the-counter'' drug. In establishing the dispensing cost elements, the Secretary might also take into account substantial differences in dispensing costs associated with different classes of vendors in different geographical locations; in the interests of administrative simplicity, however, only a small number of classes of

vendors would be established. The dispensing cost elements would be uniform for all vendors within each such class.

A number of approaches have been considered as the basis for determining reimbursement for dispensing cost. These include the following:

- A percentage markup based on the actual or estimated acquisition cost of the product.
- A fixed dispensing fee set to cover usual dispensing expenses plus reasonable profit and not related to the acquisition cost of the product.

Utilization of either approach presupposes that (a) the vendor is, in fact, aware of the actual acquisition cost of each drug, and (b) he is aware of his actual operating expenses involved in drug dispensing.

***Percentage Markup***

As described in more detail above, many vendors have traditionally established their dispensing compensation as a percentage–usually 65 to 100 percent or more–of the acquisition cost of a prescription drug product. It is based on the philosophy that the marketing of prescription drugs is, in general, not significantly different from the marketing of any other commodity.

Although it has certain disadvantages, application of the percentage markup approach has been found acceptable in many governmental and private drug programs.

***Fixed Dispensing Fee***

Based on the concept that dispensing services represent a professional function generally unrelated to the acquisition cost of a drug, some vendors have charged a fixed dispensing fee per prescription. This method now marks a number of State and Federal drug programs, including the CHAMPUS program for military dependents maintained by the Department of Defense. In the latter, for example, fees are set unilaterally by the government on a State-by-State basis and revised periodically as necessary to reflect changes in the costs of conducting business and to minimize any significant inequities.

If such a procedure were to be utilized for an out-of-hospital program under Medicare, it is presumed that the Secretary would take

into account such State or local differences, as well as differences in the business expenses of different categories of vendor establishments.

***The Task Force finds that the preferred method of reimbursing dispensing costs would depend on the nature of the program. If the program provides for a specific dispensing allowance to be paid to the drug vendor, rather than payment to the beneficiary, either a percentage markup or a fixed dispensing fee would be feasible, with a fixed fee approach being preferable.***

### *Cost-Sharing Provisions*

If reimbursement were to be made directly to the vendor, the most feasible method of sharing the cost of the benefit with the beneficiary would be for the beneficiary to be responsible for paying part of the cost of each prescription.

Many drug programs, private and governmental, in this country and abroad, have utilized such methods as co-payment, co-insurance, and restrictions on reimbursable prescription costs or prescription quantities.

In some programs, for example, the beneficiary is required to provide a co-payment of $1.00 or other specified amount for each prescription. In others, he is required to pay 20, 25 or other percentage as co-insurance. In a number of programs, restrictions are placed on the total dollar amount of any prescription for which reimbursement will be provided without special administrative approval, or on the number of days' supply of any single prescribed drug.

Although complete data are not available, there are indications from the experience of the programs in Great Britain and in North Carolina that use of co-payment reduces the number of claims and the cost of a program. Similarly, experience with the Medicaid program in Pennsylvania has indicated that use of limitations or maximum prescription prices or maximum quantities is associated with control of costs.

In terms of administrative simplicity and conservation of program funds, a fairly high co-payment amount–in contrast, for example, to a percentage co-insurance payment–would seem to be the most advantageous approach, since it would eliminate a substantial number of small claims. (Depending on the cost considerations involved in a given program, refill prescriptions could be subject either to the same flat co-payment as original prescriptions, or to a reduced co-payment amount.) Consideration might be given to placing the co-payment amount on a dynamic basis after the drug benefit had been in effect for

several years. (That is, the co-payment amount would be adjusted annually to reflect changes in the average per capita cost of drugs covered under the program.)

***The Task Force finds that any drug insurance program instituted under Medicare should include cost-sharing provisions, such as co-payment or co-insurance.***

***The Task Force also finds that consideration should be given to the use of restrictions on maximum prescription quantities or on maximum prescription prices as additional cost-sharing approaches.***

### *Limit on Amounts Paid by Beneficiaries*

While it would seem to be important for an out-of-hospital drug benefit under Medicare to place reasonable limits on the amounts that beneficiaries pay for covered drugs, preliminary consideration suggests that it may not be feasible to require that the vendor agree that the program payment for a covered drug (plus any cost-sharing amounts) would represent full payment for that drug, as is the case with respect to Part A benefits under the present program.

One important consideration is the extreme difficulty which would be involved in arriving at an audited cost with respect to each pharmacy on which to base full-cost reimbursement. Another important factor is that not all overhead costs incurred by some pharmacists may be taken into account in the ''reasonable drug charge''–an example of a cost element that may well be excluded is the cost of home delivery of prescription drugs. An additional factor is that if the program payment is based on acquisition of a drug by its generic name, but the pharmacist does not purchase by generic name, he will be incurring costs which the program would not meet. Given these considerations, it would seem necessary to permit the pharmacist to charge the program and the beneficiary together up to the amount he charges the public for a drug.

There may, however, be cases where the pharmacist would agree to accept the program payment plus the co-payment amount from the beneficiary as full payment, at least in instances where the covered drug is prescribed by generic name. Beneficiaries could be furnished with lists of pharmacies where such agreements were in effect.

Several other limitations on program payment appear to be feasible.

These include: a requirement, similar to that in present law with respect to Part A benefits, that in agreeing to participate in the program, the drug vendor would have to agree not to charge beneficiaries for any amounts that the Medicare program was liable for, or could be liable for; a requirement that, with respect to those prescriptions which fell at or below the co-insurance amount, the vendor would agree that the ''reasonable drug charge'' would be the amount at which the drug was customarily made available to the general public; and a requirement that the vendor would agree not to charge a beneficiary, with respect to any covered drug, an amount which, when added to the beneficiary co-payment and the program payment, resulted in a sum in excess of the customary charge at which the drug was available to the general public at the time the drug was furnished to the beneficiary.

## *CHAPTER 17*
## *ORGANIZATION OF HEW PHARMACEUTICAL ACTIVITIES*

The Department of Health, Education, and Welfare recognizes the substantial obligations it bears as a consequence of (a) the importance of prescription drugs to the health of all Americans, (b) the potential hazard to the health of individuals taking drugs, (c) the substantial cost of drugs purchased by individuals directly and through governmental programs, and (d) the economic investments that the drug firms have made to develop the capabilities they now possess. In discharging its responsibilities, the Department is mindful of its simultaneous obligations:

- To ensure that the drugs that are marketed are pure, safe, and efficacious for those who depend on them.
- To assure the continuing availability of effective drugs in adequate supply at reasonable prices and thus to promote the Nation's health.
- To encourage those firms that have invested their resources in the development, production, and distribution of drugs to persist in efforts to carry on their business, in ways that contribute increasingly to assure the quality of currently available drugs, and the continued discovery, development, testing, production, and distribution of significantly new and improved drugs.

- To carry on the research required to develop scientific knowledge essential for speeding drug development.
- To improve the quality of health care available to all Americans and, to this end, to encourage the rational prescribing of drugs.
- To stimulate the development of the needed scientific manpower (e.g., pharmacologists, toxicologists, and pharmacists).

In earlier reports of the Task Force, attention was directed to those aspects of drug research, manufacture, promotion, prescribing, and use which are largely the responsibility of the private sector, and its recommendations were directed toward increasing the mobilization of Federal resources to solve longstanding problems in these areas. While this section reaffirms the need for a community of interest, its findings and recommendations are concerned with those drug research and regulatory activities of the Federal Government which are largely intramural.

***Appraisal of Organization***

Recognition of both the concerns of drug users and the economic stakes of drug makers and distributors prompted the Secretary to state in his report to the President on the organization of health activities (June 1968) that he intended:

> ‘‘to examine the Department’s activities in the pharmaceutical field and to determine what, if any, further reorganization is warranted.’’

This step was planned in order to achieve these ends:

- Determine whether like or related pharmaceutical activities could be more efficiently interrelated.
- Reassess the logic of administering food and drug regulation activities within the same agency.
- Consider how an improved scientific base could be provided for the regulation of the testing, evaluation, manufacture, distribution, and promotion of pharmaceuticals.
- Appraise the existing statutory basis for drug regulation.

As a basis for considering these issues, this chapter defines and categorizes all ‘‘pharmaceutical activities’’ that are carried on within

the Department of Health, Education, and Welfare, indicates the magnitude of those activities and their current organizational location throughout the Department, and presents proposals to meet each of the four objectives posed above.

***Definition of Pharmaceutical Activities***

The Department of Health, Education, and Welfare is at one and the same time one of the Nation's largest direct and indirect purchasers of drugs, a principal stimulus for the development of new knowledge on drugs and biologicals, a principal agency for the testing of drugs, and the regulator with authority to ensure that drugs are manufactured, distributed, and promoted in compliance with the requirements of existing statutes. This substantial range of responsibilities includes the following:

*Research and the Promotion of Research*

- The screening of synthetic chemicals and natural products for types of pharmacological activity and the developing of those agents determined to be useful as therapeutic agents, particularly by the National Institutes of Health (NIH).
- The screening and development of psycho-pharmaceuticals within the National Institute of Mental Health (NIMH).
- The study of the interaction of environmental agents with man by the Division of Environmental Health Sciences of the NIH.
- The development of specially trained manpower and new knowledge in the fields of pharmacology-toxicology through efforts of the National Institute of General Medical Sciences and other institutes of NIH, and the support of medical, pharmacy and related institutions by the Bureau of Health Manpower.
- The review by the Food and Drug Administration (FDA) and the Division of Biologics Standards (DBS) of research conducted by drug and biological manufacturers in connection with the investigation of new drugs.
- The study of drug actions and interactions and of the biological equivalency of drugs, and the development of appropriate analytical methodology by the FDA.

*Regulation*

- Approval of the manufacture and distribution of new drugs, the certification of drugs containing insulin, the certification of

antibiotics, the designation of official names for drugs, and the registration of producers and certain wholesalers of drugs by FDA.

- Maintenance of a drug control system by FDA that involves (a) the inspection of manufacturing facilities, (b) routine sampling of drugs on the market, (c) the control of the advertising and other promotion of drugs to prescribers, (d) the surveillance of labeling of over-the-counter drugs to ensure that it includes adequate directions for use and any necessary warnings or precautions, and (e) the continuing assembly of reports concerning adverse reactions and their analysis.
- Licensing of biological products and of manufacturers of such products by DBS.

*Gathering, Processing and Dissemination of Scientific Information*

- Making drug information available to consumers in the form of the package inserts and monitoring by FDA of the dissemination of this information through promotion to physicians.
- Making available current drug information through the Drug Literature Program and the Toxicology Information Program of the National Library of Medicine.
- Provision of informational support for the poison control centers throughout the nation by the Consumer Protection and Environmental Health Service.
- Development and dissemination of psycho-pharmaceutical information by the NIMH.
- Assembly of drug information and information on adverse drug reactions by the FDA as a basis for its regulatory operations.

In addition there are within the Department other activities which are closely related (by function, by techniques or facilities used, or by organizational location) to those listed above. These include the following:

- Maintenance of a network of poison control centers, the collection of data through these centers, the support of research on poisoning treatment problems and related activities by the Division of Poison Control of the Bureau of Medicine, FDA.

- Establishment of safe tolerances for pesticide residues in or on foods and the review of labeling and medical hazards to operators and eventual users of pesticides, by the Bureau of Medicine, FDA.
- Development of standards for food by the Bureau of Science, FDA.
- Establishment of standards for the quality of water by the Environmental Control Administration, CPEHS.

This report is concerned with the interrelationship of each of these several activities and assesses the effectiveness of their present organizational location within the Department. It is not concerned with the organization of those units of the Department responsible for (a) the financing of the purchase of drugs under Medicare or Medicaid, the health-related programs of the Children's Bureau, or the direct health care programs of the Health Services and Mental Health Administration; or (b) the support of research and development in pharmaceuticals through grants to nongovernmental agencies.

### *Magnitude and Dispersion*

The foregoing categorization provides part of the factual understanding for assessment of logic with which pharmaceutical activities are distributed throughout the Department. To add perspective, and to indicate the balance or relative emphasis which may warrant attention, data are summarized here on (a) the annual expenditure in support of these activities by each organizational subdivision, and (b) the personnel utilized.

In total, the Department's annual expenditure for pharmaceutical activities will approximate $123.5 million in fiscal year 1968 and $133 million in fiscal year 1969. The makeup of this total expenditure is shown in Table 3.

Of this amount approximately:

- 64 percent, or approximately $85 million, will be devoted to the support of research and development;
- 2 percent, or approximately $3 million, will be used for the collection, organization, and dissemination of relevant information to all who use drugs, prescribe them, or market them to other manufacturers;
- 24 percent, or approximately $32.4 million, will be spent for regulatory activities; and

- 10 percent, or approximately $12.8 million, will be spent for standard-setting and control activities.

Because many health agency staff members devote their time to two or more related fields of pharmaceutical activity, it is not possible to give a precise statement of the individuals whose time and energies are now expended in each of the categories listed here. In general, however, approximately 3,740 individuals were employed in the conduct of ''pharmaceutical activities'' as of September 1, 1968. This total number of employees was distributed among major organizational units as follows:

| | | |
|---|---|---|
| NIH | | 560 |
| HSMHA [b] | | 190 |
| CPEHS | | |
| FDA | 2,590 | |
| ECA | 400 | 2,990 |
| | | 3,740 |

[b] The pertinent number of employees in NIMH is not readily identifiable.

### *Influencing Factors*

In appraising the organization of ''pharmaceutical activities'' throughout the Department, consideration must be given to a number of external factors that vitally affect the effectiveness with which departmental agencies carry on basic activities. These factors include:

*The substantial and still growing dependence of the drug industry on research for the development of new drugs*. This dependence creates a need for a strong research counterpart in the Federal Government that identifies areas of need and opportunity, stimulates experimentation, and collaborates with drug manufacturers in screening and appraising prospective new drugs.

*The essential separateness of the Department's two basic pharmaceutical activities.* The Department simultaneously (a) stimulates and promotes drug research and development as part of its total health research effort, and (b) regulates the manufacture, marketing, and promotion of drugs. These functions involve contrasting relations with private drug manufacturers which require performance by separate and independent agencies, under common and coordinating leadership.

TABLE 3. Annual Expenditures for Pharmaceutical Activities of the Department of Health, Education, and Welfare.

| Agency | 1965 | | 1968 | | 1969[a] | |
|---|---|---|---|---|---|---|
| | Grants & Program Contracts | Direct Optns | Grants & Program Contracts | Direct Optns | Grants & Program Contracts | Direct Optns |
| | (in thousands) | | | | | |
| National Institutes of Health: [b] [c] | | | | | | |
| NIAID | $ 2,100 | $ 4,400 | $ 2,500 | $ 7,100 | $ 2,600 | $ 7,200 |
| NCI | 22,700 | 2,220 | 19,620 | 2,630 | 19,620 | 2,630 |
| NINDB | 10,500 | —— | 13,490 | —— | 14,070 | —— |
| NHI | 447 | 129 | 3,820 | 780 | 3,820 | 780 |
| NICH&HD | 183 | 59 | 543 | 100 | 1,455 | 125 |
| NIGMS | 6,105 | 559 | 12,087 | 1,044 | 14,000 | 1,495 |
| DRFR | —— | —— | 993 | —— | 1,560 | —— |
| DEHS | —— | —— | 25 | —— | 25 | —— |
| NLM | —— | —— | 374 | 778 | 1,044 | 408 |
| DBS | —— | 4,969 | —— | 8,649 | —— | 8,499 |
| National Institute of Mental Health [c] | 7,068 | 180 | 8,147 | 200 | 8,150 | 210 |
| Food and Drug Administration [c] | —— | 17,141 | 2,817 | 26,188 | 3,175 | 29,493 |
| Related Activities– | | | | | | |
| Poison Control | 50 | 363 | 269 | 181 | 279 | 282 |
| Pesticides | N/A | 2,291 | 4,369 | 3,376 | 4,714 | 3,223 |
| Food | N/A | 1,289 | 803 | 2,671 | 574 | 3,701 |
| Total | $ 49,153 | $ 33,600 | $ 69,857 | $ 53,697 | $ 75,086 | $ 58,046 |

[a] As submitted in the President's budget, January 1968.

[b] Other Institutes of the NIH expend moneys for the development and screening of drugs as an integral part of their health research efforts. It has not been possible to distinguish these expenditures from those made for the research activities to which they contribute.

[c] NIH, National Institutes of Health; NIAID, National Institute of Allergy and Infectious Diseases; NCI, National Cancer Institute; NINDB, National Institute of Neurological Diseases and Blindness; NHI, National Heart Institute; NICH&HD, National Institute of Child Health & Human Development; NIGMS, National Institute of General Medical Services; DRFR, Division of Research Facilities and Resources; DEHS, Division of Environmental Health Sciences; NLM, National Library of Medicine; DBS, Division of Biologics Standards; NIMH, National Institute of Mental Health; FDA, Food and Drug Administration.

*The shortage of professionally trained scientists with the unique combinations of skills required for the Department's regulatory activity.* There is no present source from which can be recruited an adequate and growing supply of physicians equipped for and interested in ''regulatory medicine,'' i.e., dedicated to the protection of the public health through the rigorous, scientific evaluation of drugs. Simultaneously, there is not an adequate number of academic departments of clinical pharmacology to supply the skilled personnel needed for all Departmental activities, and on which the FDA can depend for a continuing supply of needed talent.

*The relative external prestige of the health research and the regulatory activities of the Department*. The life-saving and life-lengthening promise and results of health research endow the activities with public goodwill. That goodwill has been multiplied by imaginative and highly effective professional performance. On the other hand, the repressive, limiting character of regulatory–and, to a lesser degree, of control activities–provokes irritation, criticism, and resentment by those whose operations are affected, particularly those who violate the statutes. These underlying characteristics vitally affect the relative ability of the health research (NIH) and the regulatory (FDA) agencies of the Department to attract and hold well qualified scientific personnel for the performance of these functions.

***Assessment of the Need for Change***

In the light of understanding of the variety and magnitude of the pharmaceutical activities being carried on by the Department of Health, Education, and Welfare, and their functional relationship to other health care or consumer protection activities of the Department, these questions are pertinent:

- What regrouping or transfer of activities would make for their more effective administration?
- Would separation of the drug activities from other activities of the Food and Drug Administration make for their more effective administration?

As a part of the analysis underlying the reorganization of all health activities of the Department, careful consideration has already been given to the desirable organizational location of a number of activities closely related in varying degrees to activities of the Food and Drug Administration. This consideration has resulted in transfer of a number of activities previously carried on by the Bureaus of Health Services and Disease Prevention and Environmental Control of the Public Health Service to the Food and Drug Administration within the newly established Consumer Protection and Environmental Health Service. These include shellfish sanitation; pesticide label review, pesticide community studies and pesticide research; and poison control and the product-safety aspects of existing injury control programs.

Consideration is being given to the transfer of additional activities to the FDA–food protection, food sanitation research and food hazards

surveillance, the regulation of food handling on interstate carriers, milk sanitation, and milk sanitation research.

These several moves would constitute a significant step toward the more efficient and economical interrelationship of activities of the Department which can use common staffs, facilities or techniques, or deal with identical or related constituencies.

The inquiry on which this report is based has focused particularly on what has been defined as ''pharmaceutical activities.'' Analyses of these pharmaceutical activities make manifest that they are vital parts of the Department's efforts to improve the health and the environment of the American people.

***On the basis of numerous considerations, the Task Force finds that no gain–and a substantial loss–in operating effectiveness would result from the organizational association of all pharmaceutical and related activities.***

***More specifically, we find that:***

***The drug development and screening programs of the National Institutes are integral parts of the biomedical research effort of the NIH and should remain the responsibility of these respective units.***

***The manpower development activities of the NIGMS (support of the pharmacology-toxicology centers) and of the Bureau of Health Manpower of the NIH are logical parts of the total responsibilities of these two units. Transfer of these activities to related activities of the FDA would not yield adequate benefits to warrant such an organizational change. The pharmaceutical-related activities of the Bureau of Health Manpower should be administered as part of the total effort to expand needed health manpower by that bureau.***

***The gathering, processing and dissemination of scientific information by the Consumer Protection and Environmental Health Service and its constituent, the Food and Drug Administration; by the National Library of Medicine; and by the National Institute of Mental Health are in each instance activities that flow logically out of other responsibilities of these units. These informational activities should be retained in their present organization.***

***The regulatory activities of the DBS are not logically a part of the biomedical research activities of the NIH. The DBS, however, does carry on research and drug development activities related to the central functions of the NIH, and it benefits materially from association with the research staffs of several Institutes of the NIH. Some advantages would be gained by associating the regulatory activities of DBS with those of FDA. The DBS needs at times the regulatory skills of the FDA. But such transfer of the regulatory activities of DBS from NIH would result in the undesirable dissociation of these regulatory activities from the supporting research activities of NIH, and would cause a substantial loss in morale and probably a loss in key professional personnel. For these reasons, this action is not recommended.***

*Food and Drug Activities of FDA.* History and operating practicalities have shaped the organization of the Food and Drug Administration whereby it carries on a spectrum of regulatory, control and promotional activities dealing with foods and food additives, cosmetics and therapeutic devices, and hazardous household substances as well as drugs. The original Pure Food and Drug Act established functions common to foods and to drugs that logically and economically were administered by the same agency.

Since this agency was established, and particularly during the 1960's, important changes have taken place:

- The drug activities of the FDA have been greatly expanded, particularly as a consequence of the Kefauver-Harris Amendments of 1962.
- The number and variety of drugs subject to regulation has substantially increased.
- The technology involved in the assessment of drugs has markedly advanced.

Together these factors prompt consideration of the desirability of separating drug activities from other activities of the FDA and establishing a separate agency for drug regulation and research.

In appraising this proposal, it is necessary to consider the existing internal structure of the FDA. The staffs that make up the FDA–those that handle drug activities and those that handle activities incident to the regulation of foods, food additives and cosmetics–are intermixed

in each bureau in varying degrees; and often the same staff is engaged in both types of activities. The following data suggest the degree of intermixture and the nature of the dissolution required if this proposal were adopted.

| | Approximate Portion of Activity[a] | | |
|---|---|---|---|
| Subdivision of FDA[b] | Food | Drugs | Other |
| Bureau of Medicine | 0.5% | 94.5% | 5.0% |
| Bureau of Veterinary Medicine | 18.8 | 81.2 | 0.0 |
| Bureau of Science | 71.5 | 22.3 | 6.2 |
| Bureau of Regulatory Compliance | 46.1 | 46.1 | 7.8 |
| Bureau of Voluntary Compliance | 51.8 | 41.2 | 7.0 |
| District Offices | 56.0 | [c]38.2 | 5.8 |

[a] Based on judgments of FDA administrative staff and analysis of budget.
[b] Organizational structure as of June 15, 1968.
[c] This proportion has increased markedly in recent years; estimated approximately 50 percent in 1969.

Further examination indicates that while the internal structure of each of these bureaus would permit separation of the drug activities within the Bureaus of Science, Regulatory Compliance and Voluntary Compliance, in each instance this would cause some loss in current effectiveness and some duplication of effort in the separated agencies. Within the District Offices, which represent 50 percent of the total personnel of the FDA, the staffs are substantially involved in both food and drug activities, utilize common laboratory equipment and facilities, and could not be separated without substantial duplication of staff and facilities.

In summary, the activities involved in the regulation of food, of cosmetics and of drugs–and particularly the field investigatory activities–are carried on by the same or closely related staffs. Neither the food nor the drug activities now intermixed in the FDA can, in the short run, be economically dissected out of the District Offices and administered separately.

***The Task Force finds, therefore, that no clearly apparent benefits could be derived from the separation of drug regulatory activities from food regulatory activities that would offset the economy and efficiency now achieved through the maintenance of closely related investigatory, research, and regulatory staffs.***

***We therefore recommend that the present complex of activities now assigned to the Food and Drug Administration should continue to be administered by that agency.***

### *Survey of Drug Prices*

Increasingly, it has become apparent that the Department has an unavoidable responsibility for the continuing surveillance of drug prices because these prices are of vital concern to consumers. Included would be the accumulation of all available information on the prices of drugs, the analyses of existing indices of drug prices, the integration of drug price data–both wholesale and retail–derived by all agencies of the Department that develop or receive these data, the dissemination of information on drug prices and the results of drug price analyses, and from time to time, as circumstances make necessary, the formulation and recommendation of legislation to ensure the improved availability of drugs.

This responsibility stems from both the Department's concern that needed drugs shall be available to those consumers whose well-being depends upon them, and its responsibility for the direct or indirect expenditure (under Medicare and Medicaid) of very large sums for drugs.

At present, the responsibility for this continuing surveillance of drug prices is not fixed in any organizational unit of the Department. The Office of the Assistant Secretary for Planning and Evaluation discharged a related responsibility in 1967 in preparing its ''Report on Medical Prices.'' The Food and Drug Administration has a clearly implied obligation under existing legislation to see to it in the interest of the consumer that ''honesty and fair dealing'' prevails. If authorized by the Congress, it will produce a compendium of drugs including data on the price of each drug listed. It might therefore logically assume the responsibility for the surveillance of prices as related to other responsibilities it now discharges. The National Center for Health Services Research and Development includes a small unit of economic analysts which has carried on analyses of drug prices along with other economic analyses. Both the Social and Rehabilitation Service, because of its responsibility for coordinating the administration of Medicaid by the State governments, and the Social Security Administration, because of its responsibility for the administration of Medicare, also might be charged with responsibility for the surveillance of drug prices.

***Because the Social Security Administration has a clear concern with the prices of drugs, and possesses staffs most readily expandable to assume this responsibility, we recommend that the Social Security Administration should undertake continuing responsibility for the surveillance of drug costs, average prescription prices, and drug use.***

If the SSA is assigned such responsibility, those individuals on the staff of the National Center for Health Services Research and Development now engaged in the accumulation of data on the cost of drugs should be transferred to the Social Security Administration. The Social and Rehabilitation Service must continue to maintain a small staff responsible for assisting the State governments in the purchase of drugs by the accumulation of data and analyses of the States' experience in the purchase, use, and cost of drugs.

***Improvement of Scientific Capability***

If, as is proposed, no substantial organizational change is made, there will remain the urgent need to improve the scientific capability of the staff responsible for drug regulation. This important need grows out of the substantial expansion of FDA's responsibilities for drug regulation within recent years and the difficulties encountered in recruiting qualified professional personnel. To meet this need, the FDA has taken significant steps to:

- Attract more and better qualified professional personnel, particularly physicians, by making employment arrangements more attractive, by developing orientation programs to acquaint those who are recruited with the full panoply of the Department's pharmaceutical activities, by (a) offering individuals opportunities for simultaneous clinical and/or research experience, while serving the FDA, and (b) providing leaves of absence for educational and research assignments.
- Supplement the capabilities of the FDA's in-house staff by contracting with medical schools throughout the country (as has been done with the Georgetown Medical School) and by seeking ways of making fuller use of the Public Health Service hospitals for supportive clinical research.

*Immediate Opportunities*. These steps alone are not enough. The critical nature of the problem of enhancing the scientific capabilities of

FDA's staff is made more pressing by the necessity of (a) acting upon the recommendations of the NAS-NRC drug study, and (b) finding replacements for those physicians who were assigned by the PHS to assist the FDA and whose assignments are now being completed.

***We therefore recommend that efforts should be strengthened to assure that the skills of experts both within and outside of the Department of Health, Education, and Welfare are used to augment the scientific capabilities of the Food and Drug Administration.***

This might be accomplished, in part, by enlisting the assistance of individual scientists from health agencies within the Federal Government to serve for limited periods on tasks which they deemed relevant to their research interests, or by their acceptance of *ad hoc* assignments for the evaluation of specific drugs or other priority work.

In addition, the Commissioner of Food and Drugs should strengthen the efforts to establish a full and continuing association of the Food and Drug Administration with the Nation's medical schools, pharmacy schools, and the biomedical scientific community. This might include contracting with relevant specialists on the staffs of the five medical school faculties in the Washington area to assist with the review of Investigational New Drug exemptions (IND's) and New Drug Applications (NDA's).

These efforts should also include the substantial expansion of the current use of advisory committees. It is particularly proposed that the FDA be directed to explore the feasibility of establishing a series of *ad hoc* panels made up of the best relevant medical and scientific talent throughout the country to assist with the review of IND's and NDA's for all new chemical entities or other drugs submitted for approval.

Review of IND data and NDA's by personnel outside FDA would pose problems concerning the maintenance of the confidentiality of material submitted for review by drug manufacturers. We believe, however, that adequate safeguards can be established to ensure the protection of the interests of the manufacturers. The value to be derived from the association of the FDA staff with outstanding talent throughout the country, i.e., the enrichment of the experience of staff personnel and the authoritativeness added to FDA decisions made after consultation with such panels, would be so great as to warrant an early and substantial effort to bring these panels into being.

*Long-Range Opportunities*. In addition, three alternative proposals for enhancing the scientific capability of the FDA's drug evaluation staff have been considered. These proposals are as follows:

1. A ''Therapeutic Appeals Board'' should be established within (or without) NIH to provide both scientific and clinical capabilities, supplementing those possessed by the FDA. It would be provided with staff and facilities to carry on basic research and clinical studies through association with both Federal and non-Federal health facilities. These facilities would be utilized to study and evaluate selected drugs submitted by manufacturers or by the FDA, when an NDA has been refused approval by the FDA.
2. An Institute of Pharmacology should be established within the NIH to carry on research in the field underlying the regulatory function of the FDA and to administer the program of support for the pharmacology-toxicology centers.
3. A clinical and laboratory facility should be established within the FDA to concentrate on research concerned with the use, efficacy, and toxicity of drugs, and the development of new methods and approaches to their evaluation. It would provide opportunities within FDA for a continuum of research and application extending from molecular pharmacology through animal testing to clinical experience.

Such a center could pursue a multi-disciplinary approach combining the efforts of pharmacologists, toxicologists, clinical investigators, biochemists, experimental pathologists, medicinal chemists, geneticists and perhaps others. It would require laboratory and clinical facilities. And it would need to have an effective system of communication with several institutes of the NIH, and particularly with the National Institute of General Medical Sciences and the pharmacology-toxicology centers which that institute supports.

*A Choice Among Alternatives*. Each of these alternative proposals would provide supplementary laboratory and clinical research facilities and thus enhance the existing capabilities of the Bureau of Medicine of the FDA by:

- Strengthening the scientific aspects of drug evaluation, and probably modernizing methods; and
- Attracting (in various degrees) a greater number of men and women possessing medical and scientific competence to these activities.

The alternatives differ in that (a) the ''Therapeutic Board'' would combine research and appeal responsibilities, (b) the Institute of Pharmacology within NIH would have both a research and a manpower function, and (c) the FDA drug research facility would provide a broadly based research effort.

But each of the first two proposals would separate drug research activities from drug regulation activities. Such organizational separation would establish an artificial and unnatural divergence between the agency responsible for fact finding and the agency responsible for acting on those facts.

The proposal for a ''Therapeutic Appeals Board'' poses an added organizational handicap. Acceptance of this proposal would establish a supplementary capability, of necessarily limited competence, and, by providing an added appeals opportunity for drug manufacturers, would undermine the regulatory strength of the FDA.

Establishment of a research capability within NIH, i.e., the establishment of an Institute of Pharmacology, would ''borrow'' from the competence, reputation, and prestige of that agency to increase the capability of FDA. It would, however, be an illogical organizational arrangement within the NIH; pharmacology is, among other things, a tool discipline used by many or all existing institutes, and all research in or use of this discipline cannot properly be concentrated in a new and separate institute. Moreover, establishment of such an institute would give no assurance of better relating the NIH capabilities with the needs of FDA–a notable lack to date. The use of relevant experts on the NIH staffs to assist FDA on specific problems in which they have a special interest and competence offers a greater likelihood of making NIH's substantial capabilities available to the FDA, and accordingly ''separate'' capability will be less needed.

In the long run, it is essential that the capability of the Bureau of Medicine itself be increased both by (a) the upgrading of the existing medical staff and (b) the inclusion in this Bureau of supplementary scientific personnel equipped with the facilities needed for carrying on relevant research.

***Because it constitutes the preferable means for creating the additional scientific capability that is required, the Task Force recommends that legislation should be enacted to authorize establishment within the Food and Drug Administration of a clinical and laboratory facility to provide the necessary***

***opportunities for research by highly qualified basic scientists and clinicians.***

In recognition of the substantial contributions of the late Senator Royal S. Copeland toward enactment of the present Food, Drug and Cosmetic Act, we propose that this facility be known as the Royal S. Copeland Research Center.

***Reappraisal of Drug Evaluation Methods***

In addition to increasing the scientific capability of the regulatory staffs, there is need for reappraising the relevance and efficiency of methods now used by DBS and FDA to evaluate the safety and effectiveness of pharmaceuticals.

Three methods are now used:

1. The approval of new drug applications by FDA is substantially an assessment of the research evidence presented in support of the safety and effectiveness of pharmaceuticals. It also includes a critical evaluation of manufacturing facilities and verification of the strength, quality and purity of drugs and of the proposed manufacturing and control procedures. The approval granted for the distribution of a new drug may be withdrawn for cause.
2. The certification of antibiotics and insulin by FDA involves initial approval by the methods described in the preceding paragraph, and in addition, the analysis of every production batch before distribution. Batches which do not comply with applicable regulations are denied certification, and cannot be distributed legally. Certification may be discontinued at any time if conditions of certification are violated.
3. The approval of biologicals by DBS involves the licensing of both the establishment and the product, and the subsequent review of control protocols and/or continuing study of samples.

These methods are now founded in legislation as well as in historical practice. Yet the logic or necessity of these methods is subject to substantial and widespread questioning, and their suitability deserves careful examination.

To help assure the uniform high quality of drugs marketed in interstate commerce, the Task Force earlier recommended consideration of a licensing and registration system for drugs and drug producers. The

favorable experience of DBS and of pharmaceutical control authorities in other countries suggests that such a system can also be used for the evaluation and premarketing clearance of new drugs.

> ***The Task Force therefore recommends that the Secretary of Health, Education, and Welfare should, after consultation with representatives of the drug industry, pharmacy, clinical medicine, and consumer groups, should appoint a study group to reappraise the efficiency of methods now used by the Division of Biologics Standards and the Food and Drug Administration to evaluate the safety and effectiveness of pharmaceuticals. The participants should direct attention to the appropriateness of the three existing classifications of pharmaceuticals–new drugs and "not new" drugs, certifiable products, and biologics. The study group should also consider the feasibility of developing a registration and licensing system which would assure that all drugs marketed in interstate commerce are produced under adequate quality control standards.***

Consideration of such a system will inevitably involve a simultaneous assessment of the combined industry-government effort to discover new drugs and to bring them promptly from the research laboratory to the patient. The effectiveness of this combined effort requires, on the one hand, that the research conducted by industry and the reports of this research submitted as a basis for the approval of the FDA and DBS be thorough, competent and persistently reliable; and, on the other hand, that the review of these research reports by the scientists of FDA and DBS be equally thorough, competent and reliable.

## *CONSULTANTS AND WORKSHOP PARTICIPANTS*

During the 20 months of its operations, the Task Force and the Task Force Staff were particularly fortunate in having the advice, guidance, support and criticism of more than 160 nongovernmental experts representing clinical medicine, pharmacology, pharmacy, medical and pharmacy schools, professional health organizations, drug manufacturing, drug distribution, health insurance, data processing, economics, law, and a variety of consumer groups.

Some of these individuals served as formal consultants to the Task Force, others served informally, and still others participated in

workshops and other Task Force conferences. Many of them gave generously of weeks or months of their time, providing assistance which was invaluable to the Task Force in its work.

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Their listing here in no way suggests that any of them have approved or disapproved the Task Force findings and recommendations.

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